Patients with osteoarthritis in primary care

Thomas Rosemann

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Patients with osteoarthritis in primary care

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op het gebied van de Medische Wetenschappen

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Contents

Introduction

This thesis focuses on the quality of life and the quality of primary care in osteoarthritis (OA) patients. Even though this affection of joints is a highly prevalent disease and its prevalence is increasing, little is known about this topic. Thus, the overall aim of this thesis was to describe and analyse various aspects of the quality of life in OA patients and the primary care they receive. In the first section of this thesis several measures of quality of life of patients with OA will be examined. In the second section, comorbidities and their influence on the quality of life and health service utilisation (HSU) are explored. In the final section, the currently provided primary care and approaches to its improvement will be studied.

Osteoarthritis

DEFINITION

Osteoarthritis is the most common affection of joints worldwide.[1] Interestingly, there is no consistent definition of osteoarthritis.[2] It can be defined by either symptoms or pathology. In contrast to prior ideas, nowadays, OA is regarded not only as an affection of the cartilage or joint alone.[3] The pathology involves the whole joint in a disease process that includes cartilage loss with concomitant changes in the bone underneath the cartilage, including marginal outgrowths (osteophytes) and bone sclerosis.[4] Also the soft tissue is involved in this complex process, including synovium, ligaments and muscles. The synovium often shows modest inflammatory infiltrates, the ligaments are often lax, and the muscles are often of reduced strength: supporting a hypothesis which favours joint stability as important predictor of OA. It is still unclear whether OA is a single disease or a combination of many disorders with a similar final common pathway.

The clinical definition takes into account the pathology, resulting in functional disability and pain occurring with joint use. But interestingly, in detail, the cause of the pain is unknown.[5] It is regarded as a result of the complex interaction between the structures in and around the joint which are involved in the use of the joint.[6]

Prevalence

Regarding the prevalence, it is important to distinguish between the radiological prevalence and the prevalence of symptomatic OA.[7-9] To develop radiological signs of degenerative affections of the joint seems almost unavoidable: in the general population over 50% of the women aged 80 or over have radiological signs of osteoarthritis.[7,10] But fortunately X-ray findings do not hurt: the prevalence of symptomatic osteoarthritis is notably lower. Nevertheless, according to estimations of the WHO, about 9% of men and 18% of women suffer from

symptomatic OA.[1] The prevalence of diagnosed OA in healthcare is lower than in the open population. Data from the Netherlands (based on the International Classification for Primary Care, ICPC) for instance showed a prevalence of hip OA of 3.8%, of knee OA of 5.6% and 4.0% on other joints, diagnosed in a primary care population.[11]

Interestingly, the prevalence patterns change with the age of the observed population: before the age of 50, the prevalence of OA in most joints is higher in men than in women.[3] After the age of 50, women are more often affected, especially with OA to the knee, whereas men are more affected by OA to the hip. Since its prevalence and incidence is expected to rise in the upcoming years – at least in the industrialised countries – the World Health Organization (WHO) has declared this decade as "bone and joint" decade.[12] Regarding the localisation of OA, the knee and the hip are the mostly affected joints.[13]

Risk factors

Among risk factors for emergence and prognosis of OA influenceable and non-influenceable factors have to be distinguished. Regarding non-influenceable risk factors, many studies have shown that genetic factors account for at least 50% of cases of OA in the hands and hips and a smaller percentage in the knees.[14] The strongest non-influenceable risk factor is age.[15] With increasing age the probability to develop radiological signs of degenerative changes in the joints increases.

Especially for the knee, weight load and stability are the most important influenceable factors. Therefore, increased body weight represents the strongest predictor for developing OA.[15,16] Strengthening the muscles, especially the musculus quadriceps femoris, increases the stability of the knee joint and lowers the risk of OA. This is not only effective in primary prevention, studies have also shown that strengthening muscles can reduce pain and increase functional ability in patients who suffer already from symptomatic OA. Unfortunately, many people are not very physically active.

Quality of life in patients with osteoarthritis in primary care

Few studies of the quality of life in OA patients have involved large samples of primary care patients or the general population. Some epidemiological studies included risk factors or other epidemiological aspects.[8,10,20] Therefore, in the first section of this thesis the problems and needs of OA patients in primary care will be assessed and measures of their disease specific quality of life (QoL) will be

examined. Since it is also unclear how GPs estimate the QoL of their OA patients, we will assess this issue in a separate study.

OA shows a strong association to the body weight, obesity respectively.[21-23] But obesity is also an important risk factor for many other diseases, especially cardiovascular diseases.[24] How comorbidities influence QoL in OA patients and health service utilisation (HSU) has only been marginally assessed so far. Furthermore, chronic diseases as OA often influence many dimensions of the QoL as for instance, affective aspects. Depressive disorders are often increased in patients with chronic diseases.[25-27] Psychosocial aspects are important for the clinical management of the disease and also influence HSU substantially. Pain for example, one of the biggest burdens of OA, was strongly associated with depression.[28,29] Depression has a detrimental effect on physical activity, which is important to strengthen muscles and keep patients mobile.[28,30] Regarding all these aspects only little research is currently available, especially from large samples of primary care patients. Therefore, in section two of this thesis the prevalence of comorbidities and determinants of depression and pain and their association with obesity and HSU will be assessed.

Chronic care model

Due to the demographic trend in most industrialised countries, chronic diseases like arthritis, diabetes, hypertension and asthma are expected to increase tremendously in the upcoming years.[31] They may represent the biggest challenge for the health care systems in the near future, not only from a medical but also from a societal perspective. Current care, also for the chronically ill is often dominated by reactive and event-driven approaches which will not succeed in delivering appropriate, patient-centred care. Ed Wagner and colleagues developed a Chronic Care Model (CCM).[32,33] The CCM represents a broad conceptual framework that aims to overcome the increasing and well-documented gap between clinical research findings and real practice.[34] It supports evidence-based proactive and planned care for chronic diseases instead of event-driven and unplanned activities. It specifies six broad dimensions: organisation of health care, clinical information systems, delivery system design, decision support, self-management support and community resources. In this thesis, the chronic care model is used as a broad framework to examine approaches for the improvement of primary care for OA patients. Particularly, the thesis will explore which components of the model can be effectively implemented in German primary care – physician orientated medical care, delivered in small practices.

A recent review of the literature confirms that successful improvement strategies concerning chronic diseases are consistent with the concept and components of the CCM.[35] The needs of chronically ills and consequently the requirements on health care providers are quite similar in many chronic diseases. Even the effective interventions applied in a proactive approach are similar to some other chronic diseases: for example, similar to hypertension or diabetes, a reduction in body weight has proven to improve pain and functional disability.[22] Therefore, the CCM seems to be appropriate for various chronic diseases[36] such as hypertension, diabetes[37,38] and also arthritis. But some limitations of complex approaches as the CCM have to be acknowledged: the concept has been developed in large Health Maintenance Organization (HMOs) in the US, which provide a large variety of health care professionals. Primary care, especially in Germany, is very physician centred. Currently it seems not possible to provide care according to the CCM in primary care in Germany; even recent findings indicate that required changes in practices are small. Taking into account the lack of young GPs and the expected decrease in numbers of GPs providing primary care, delegating work will be indispensable in the care for chronically ills. As a consequence, primary care will most likely shift from a physician centred system to a team structure in care, even in Germany. In consequence, it seems interesting to assess – compared to a conventional, physician centred approach - a team approach. In section three of this thesis a qualitative approach on this issue, as well as the realisation of a team approach in a large cluster randomised-controlled trial, is presented.

Aims and objectives

The central aims of this thesis were

1. to assess the quality of life of patients with osteoarthritis in general practice and to validate appropriate instruments (chapters 1 to 3).
2. to reveal the impact of concomitant complaints and conditions on QoL and health service utilisation (chapters 4 to 7).
3. to assess the care provided, reveal possible improvements and to evaluate their impact in a randomised controlled trial (chapters 8 to 11).

Table 1 gives an overview of the specific objectives and the associated chapters addressed in the three main sections of this thesis:

Aim of the section	Objective of the specific chapter
I. To assess the quality of life of patients with osteoarthritis in general practice and to validate appropriate instruments	1. To assess problems and needs of OA patients in a qualitative study 2. Validation of the short and long form of the Arthritis Impact Measurement Scale (AIMS) 3. To assess determinants of GPs estimation of patients' QoL
II. To reveal the impact of concomitant conditions, on QoL and health service utilisation	4. To assess prevalence and determinants of depression 5. The influence of depression on quality of life and HSU 6. The determinants of pain in OA patients 7. The effect of obesity on QoL and HSU
III. To assess the provided care and to evaluate a case management approach	8. Association of patient satisfaction and disease specific quality of life 9. Congruency of provided care with the Chronic Care Model 10. Involvement of the practice nurse in the treatment of OA patients 11. The effect of case-management provided by practice nurses

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Section I

Quality of life

Chapter 1

Problems and needs for improving primary care of osteoarthritis patients: the views of patients, general practitioners and practice nurses

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Abstract

Background: Osteoarthritis (OA) is highly prevalent and has a substantial impact on the quality of life as well as on healthcare costs. The general practitioner (GP) is often the first care provider for patients with this chronic disease. The aim of this study was to identify health care needs of patients with OA and to reveal possible obstacles for improvements in primary care management of OA patients.

Methods: We performed semi-structured interviews with a stratified sample of 20 patients, 20 GPs and 20 practice nurses.

Results: Diagnosing OA posed no major problem, but during the course of OA, GPs found it difficult to distinguish between complaints resulting from the affection of the joints and complaints related to a concomitant depression. Patients felt to be well informed about the degenerative nature of the disease and possible side effects of medications, but they lacked information on individual consequences of the disease. Therefore, the most important concerns of many patients were pain and fear of disability which they felt were only marginally addressed by GPs. Regarding pain treatment, physicians and patients had an ambivalent attitude towards NSAIDs and opiates. Therefore, pain treatment was not performed according to prevailing guidelines. GPs felt frustrated about the impact of counselling regarding lifestyle changes but on the other hand admitted to have no systematic approach to it. Patients stated to be aware of the impact of lifestyle on OA but lacked detailed information, e.g., on how to exercise. Several suggestions were made concerning improvement.

Conclusion: GPs should focus more on disability and pain and on giving information about treatment since these topics are inadequately addressed. Advanced approaches are needed to increase GPs impact on patients' lifestyle. Being aware of the problem of labelling patients as chronically ill a more proactive, patient-centred care is needed.

Background

About 10% of men and 18% of women aged 60 years and over suffer from symptomatic osteoarthritis (OA)[1]. Due to increasing life-expectancy as well as constant increase in the average body mass index, which constitutes a principal risk factor for OA [2], the incidence of OA is expected to rise in years to come[3]. OA causes high direct costs (0.7 % to 1.2 % of the gross national product), and also high indirect costs as a consequence of morbidity and disability and represents one of the diseases with the highest economic impact [4-7].

The main care provider for many patients with OA is the GP[8,9]. To improve quality of care for osteoarthritis patients, evidence-based guidelines and a quality indicator set exist in most countries; however, this is not the case in Germany [10,11].

It has been suggested that conservative management of OA is difficult for physicians and patients, but little is known about the actual management of OA in primary care in Germany. Moreover, there is only limited information on the perspectives of different groups involved in the treatment of OA[12]. For instance, practice nurses play an increasing role in providing care in many health care systems, but their perspective is often ignored[13,14]. Insight into patients', physicians' and practice nurses' views on management of OA is needed to identify problems concerning quality of care and possibilities for improvement. The aim of our study was to reveal patients' needs, assess their wishes for improvement and to identify obstacles that handicap improvements. In order to implement such improvements, it is important to not only assess the views of patients but also those of doctors and practice nurses. The interview guideline was created according to our hypothesis that patients lack information on the disease, medication and possible approaches and wish for more consultation time. The results of this study should help create interventions for the primary care setting to be evaluated in a subsequent intervention study.

Methods

A qualitative interview study with general practitioners (GPs), practice nurses and patients with OA was performed according to the guidance for qualitative research[15]. A heterogeneous sample of 20 GPs, 20 practice nurses and 20 patients was stratified by gender and urbanisation level[16]. The GPs had to have a minimum of 5 years experience; the assistants were required to have a minimum of 10 years professional experience. The patients were selected at random from the GPs' computer files by searching for patients with the ICD -code M16.0–16.9 (coxarthrosis) and M17.0–17.5 (gonarthrosis). During their practice visit they were

asked by the GP if they wanted to participate in an interview. All patients but one agreed to participate. The study protocol (named as "PraxArt-barriers-study") has been approved by the ethics committee of the University of Heidelberg; approval number 019/2004.

Interviews

After a detailed study of the literature on evidence-based, non-surgical treatment options for OA and regarding patient perspectives in chronic diseases, we compiled a semi-structured interview guide with open-ended questions.

All interview guidelines were as similar as possible to allow comparisons across groups and followed the normal course of a consultation: diagnostic routines, information giving, prescribing, advice on lifestyle change and referral. Due to the small number of non-surgical evidence-based treatment options we were especially interested what importance evidence-based treatments have. In addition, we focused on the attitudes of patients, doctors and assistants towards a larger involvement of the practice nurse in the care of patients suffering from OA.

Procedures

The interviews were conducted during 2004. The GPs and practice nurses were interviewed in their respective practices; the patients were interviewed at home by trained interviewers. During the interview, the interviewer ensured that every aspect was explained sufficiently and in detail so that there would be no questions or misunderstandings later on.

Analysis

The conversations were recorded digitally, transcribed literally and analysed by four different researchers with ATLAS.ti-Software[17]. An initial categorising system was established based on the interview guidelines. In order to achieve maximum objectivity, all interviews were read by four researchers and categorised independently. The categorising system was consequently modified; subcategories were added after agreement had been reached among all four researchers. Numerous free categories were developed from the text, discussed and adjusted in an iterative process so that they were as similar as possible in all three interviewed groups, as the objective was to emphasise the different perspectives of the groups regarding individual subject complexes. The codes were clearly defined and linked with representative examples from the original text.

Results

The mean age of our patients was 56, with a range from 40 to 78 years as can be seen in table 1. The educational level was relatively high. Working experience ranged from 8–19 years with a mean of 11.3 years among GPs and from 13–35 years (mean: 21.7) among practice nurses. Some items yielded very limited responses among practice nurses; therefore their statements were only mentioned if they provided an important contribution to a specific aspect.

Table 1. Baseline characteristics of the study sample

	N (female)	Age (mean)	Years of working experience (mean)	Education level * (mean)	Interview time (minutes)
practice nurses	20 (20)	29-56 (41.3)	13-35 (21.7)		25 (21-34)
GPs	20 (4)	33- 57 (43.5)	8-19 (11.3)		45 (41-60)
patients	20 (12)	40-78 (56.2)		3.3	43 (41-55)

* (1= no school; 5=university degree)

Tables 2, 3, 4 display the categorical system with subcategories. The numbers in brackets display how many participants responded to the respective category.

Diagnotic aspects – proceedings

The interviewed GPs stated that in most cases diagnosing OA poses no major problem to them. The diagnosis is frequently based on an extensive anamnesis and an accurate examination. The interviewed GPs stated that if they are unsure whether the pain is caused by the joint or periarticular structures, an X-ray is performed to confirm OA. During the course of OA, the situation is more difficult: it sometimes represents a challenge for GPs to distinguish between complaints resulting from the joint affection and complaints which are mainly related to depressed mood. Satisfaction among patients regarding the diagnostic procedure was high: most patients in our study sample stated that the GP took enough time in diagnosing and that the examination was extensive and accurate.

When asked about how and to what extent GPs inform patients about the disease, some GPs stated that they try to assess the patients' need for information and their capability to understand, but also what they assume the patient can handle. Overall, patients were considered to be well informed due to their utilisation of countless other sources of information such as print media and TV.

This assumption was confirmed by many patient statements. Regarding the cause and the pathomorphology, patients felt well informed. Most of them were aware of the degenerative nature of the disease. There was no apparent lack or request for more information on this topic. But in terms of the prognosis, patients were very

insecure. Pain and becoming disabled were the main fears of patients, and most of them stated that they were insecure to what extent the pain could increase and if they would still be able to walk at some point in the future. Many patients argued that physicians were mainly focused on explaining the pathology of the disease and the treatment options such as new surgical methods but less focused on their main fears. Especially older patients seemed to have problems mentioning these concerns. In conclusion, there was no quantitative lack of information, but a qualitative one, as the following two statements reflect:

> *"The majority of patients nowadays open the envelope (of the specialist) themselves. They know exactly what is written down there. There is communication on the same level between doctor and patient."* (GP 10, male, aged 37)
> *"I know that OA is a one-way-street. That's not the problem. Life is a one-way-street too. But in OA I don't really know what's at the end." (Patient 17, male, aged 71)*

Diagnotic aspects – problems

Asked about problems in the diagnostic process, most of the interviewed GPs were aware that like many other diseases of the musculoskeletal apparatus, OA only shows little correlation between what is pathomorphologically visible – e.g. on a radiographic image – and subjective complaints. Therefore, many GPs stated that they found it difficult to assess to what extent complaints originate from arthritis and what part of the complaints are due to concomitant depressive symptoms. This was particularly the case when there was insufficient radiographic evidence and the physical examination gave no sign for an acute inflammation of the joint. Depression was also recognised as an important barrier to motivate patients to take physical exercise. Concrete instruments such as well known questionnaires for instance the HAMDS[18] or the PHQ-9[19] etc. were not used to reveal depression.

One GP stated:

> *"And there is always a depressive component. The relation between depression and arthritis pain and physical sensation is an important one. And exactly those people with depression cannot change anything about it, because they really suffer from depression and are not capable of changing their lives or doing something about their lives; they fall deeper*

and deeper into this vicious circle of disease and pain, and nobody can help them." (GP 5, male, aged 47)

According to GPs' statements, and confirmed by most patients of our sample, nearly every patient was sooner or later referred to an orthopaedic surgeon in order to confirm the diagnosis by taking an X-ray.

"He was more interested in taking pictures of my knee than in examining it". (Patient 19, female, aged 68 on an orthopaedic specialist)

Table 2. Main categories regarding diagnostic aspects

General Practitioners	Patients	Practice Nurses
Proceedings[a] (19)[b]:	***Satisfaction (20):***	***Involvement (20):***
Making an extensive anamnesis [c] (19)	Satisfied with diagnostic	Current involvement in
Making an extensive examination (18)	proceedings (15)	- diagnostic proceedings (2)
Informing patients about cause and	***Needs/problems regarding GPs***	- treatment (1)
course of disease (17)	***(13)***	No involvement in diagnostic
Referring patients to orthopeadic (8)	Missing information about	proceedings (17)
Referring to radiologist (6)	diagnosis and its course/impact	Wish of being more involved (11)
Problems	on individuals life (12)	No wish of being more involved
- diagnosing OA (12):	Lacking time (2)	(9)
Poor correlation between x-rays and		
complaints (8)	***Needs/problems regarding***	***Barriers against involvement***
Concomitant depression (5)	***specialists (15)***	***(20)***
Others (3)	Lacking time (14)	Lacking knowledge about disease
- regarding specialist (6)	Missing information about	(13) / treatment (17)
Focusing on performing x-rays (5)	diagnosis and its course/impact	Lacking time due to -
Missing information about performed	on individuals life (8)	administrative overload (11)
examinations/ recommendations (5)	Focussing on performing	- other reasons (3)
Felt pressure to refer to specialist (3)	examinations (5)	
	Recommendation of expensive	
	treatments (4)	

[a] Words in italic are main categories;
[b] number of participants referring to the respective category (multiple mentions possible)
[c] subcategories (not all subcategories are displayed).

Patients regarded specialists as an additional source of information, but most of them mentioned that the GP took definitely more time for the anamnesis and was often more accurate than the specialist. Many patients stated orthopaedics would be mainly interested in the use of machines then in talking to them. GPs also had an ambivalent attitude towards these referrals. On the one hand they did not recognise superiority in knowledge and treatment options of a conservative treatment by an orthopaedic surgeon. On the other hand they used the orthopaedic surgeon from time to time to escape from the psychological burden induced by the patient and the absence of treatment options. In addition they felt a

lot of pressure by patients to refer them to the specialist, especially in the case of younger and well-educated patients. But some stated that they sometimes felt abused by patients as well as by specialists, because the patients pushed them to be referred and the specialist did not take the time to explain what they had examined or the X-rays he had taken. Therefore, GPs often ignored the patients' repeated requests for referrals to an orthopaedic specialist.
Interestingly, lack of time could not be revealed: most GPs stated to take as much time as possible and patients did not regard time limitation as a main problem or at least showed understanding for the limitation in the face of overcrowded waiting rooms.

Treatment aspects – pharmacological treatment
Regarding treatment aspects, pharmacological treatment was the topic on which the most statements were recognised, indicating the importance of this topic for all groups. Facing decreasing financial resources and increasing restrictions by most health insurances, many GPs stated that treatments like massages, physiotherapy and manual therapy were prescribed less frequently. Some GPs complained that in consequence OA treatment has been reduced to mainly prescribing pain medication.
Asked about adherence to guidelines, which recommend Paracetamol as first choice of pharmacological treatment[20-22], GPs stated that Paracetamol was not accepted as a real pain reliever because it is known to most patients as medication for "headache" and available without prescription. GPs also argued that most patients have already taken this drug on their own by the time they visit their physician.
Consequently, Paracetamol was prescribed less by the interviewed GPs, and for all of them NSAIDs represented the main pillar in their pharmacological therapy of OA. But after the withdrawal of most COX-2-inhibitors, patients as well as doctors felt very uncertain what to consider as an appropriate pharmacological treatment.
Interestingly enough, patients and GPs have a similar ambivalent attitude towards analgesics. Patients appreciated the alleviation of pain, but at the same time they instinctively rejected these drugs without an apparent rational explanation. For instance, Diclofenac's stomachirritating potential is such a well-known fact that positive aspects of the drug are being ignored. No patient stated that he would take pain relievers in advance; they normally wait until they cannot take the pain any longer. GPs felt that due to the package inserts patients mainly focused on side effects; and therefore these leaflets were regarded as a barrier for optimal

treatment compliance. GPs' main aim was to ensure that the patient actually took the prescribed drugs. Therefore, they had mostly developed individual strategies that consisted of a balancing act of explanations for anticipated objections regarding treatment, legal requirements and belittlement.

Asked about the meaning of package inserts, most of the patients stated that information on side effects was not that important to them, because they were aware that many of the side effects mentioned on the package insert never occurred. On the other hand they generally read the package inserts. Most patients of our sample stated that they mostly trusted the information given by their GP. But it seemed that the package inserts alerted them for possible side effects. In conclusion patients as well as doctors are more focused on side effects then on positive effects such as the anti-inflammatory potential of NSAIDs.

The following statement displays the strategy of one GP in dealing with side effects:

> *"Well, my personal opinion is, if you give the patients two or three side effects, they are happy, otherwise they have all of them since they are printed on the package insert. For that reason, I limit myself to two or three that I mention. Sometimes, when you mention it and say,"oh you could get that, but not really, only a few get that", I always attach a negative example, "but I think you are quite fit and healthy, so that you will not get it", then they don't get it.* (GP 3, male, aged 51)

Table 3. Main categories regarding treatment aspects

General Practitioners	Patients	Practice Nurses
Applied (non-surgical) treatments (20):	***Needs/Expectations (20):***	***Knowledge (20):***
Prescribing Pain relievers (19)	Improvement of symptoms	Knowledge about treatment (18)
Prescribing physiotherapy/ massages (3)	- pain (14)	No knowledge about treatment (2)
Counselling (19)	- physical activity (8)	
- to reduce weight (19)	Pointing out possible treatments (5)	
- to exercise (15)		***Involvement (20):***
- others (2)	Conversation about the problems (2)	Involvement in treatment (2)
Problems (20):	Referral (2)	No involvement in treatment (18)
General (14):	***Problems (20):***	Wish of being more involved (14)
- Increasing restrictions regarding prescription of physiotherapy, etc. (14)	*Regarding medication (20):*	No wish of being more involved (5)
- Lack of time (3)	- (Fear of) side effects (16)	
Regarding pharmacological treatment (20):	- Lacking pain relief (12)	
- Package leaflets decrease adherence (14)	*Regarding counselling (15):*	
- Insecurity with pharmacological treatment/guidelines (12)	- reasons laying in individual behaviour (14)	
- Little acceptance of opiats (6)	- no precise advices to reduce weight/exercise (8)	
- Interaction with specialist (5)	- lacking information about supportive offers (6)	
Regarding lifestyle:		
- Motivating the patient to exercise or reduce weight (17)		
- Concomittant depression (6)		

Regarding opiates, similar barriers could be revealed from the doctors' as well as from the patients' perspectives: GPs stated that many patients would reject these "heavy drugs" (GP 6) and it seemed that even GPs regarded use of these drugs as overtreatment in OA. Furthermore, most physicians stated not to prescribe them as they are poorly tolerated and cause nausea. Opiates were often recognised by patients as medication for people in very poor condition such as, e.g., cancer patients and therefore rejected. None of the patients received a structured pain treatment plan or systematic advice to cope with pain. The following statement of a patient (female, 76) reflects a quite typical statement:

> *"But I am careful; if I can take the pain then I won't take a pill because they are not really good for you. Only if there is no other way, then I will take one and that has to be enough....I really only take a pill when I am in terrible pain, otherwise I am against drugs."* (Patient 4, female, aged 71)

Treatment aspects – advice giving and counselling

This topic received the second most statements from GPs and patients. Nearly all interviewed GPs emphasised that they repeatedly addressed behaviour

interventions that can slow down the progress of OA, including weight loss and the strengthening of musculature. However, most of them admitted that they did not focus on increasing patients' motivation for behavioural change, but just gave general recommendations. The success rate in motivating patients was considered too low by the GPs, and the majority appeared distinctly resignated regarding their impact on patients' lifestyle. Many GPs also mentioned that there was a vicious circle: due to pain when exercising, people move less and eat more due to accompanying frustration and sometimes depression. When asked about the reasons why it is so hard to communicate these secondary preventive measures to patients, most GPs answered as GP 17 (male, aged 54):

> *"Osteoarthritis is ultimately only a symptom of a huge lifestyle problem a complete change in lifestyle is required.... and this is impossible for osteoarthritis patients who are mostly elderly people... nobody is willing to change his/her lifestyle due to osteoarthritis, the disease has to be a lot worse than this. People have basically learned to live with it. "*

The patients in our sample confirmed GPs' statements regarding lifestyle interventions. The majority indicated that their GP had tried to motivate them repeatedly and had explained the general effects of lack of exercise and overweight. The following statement displays this quite impressively:

> *"He really talked to me again and again, once he even asked if I wanted to eat myself into a wheelchair. And if I don't do it then it is my fault. The spirit is willing, but the flesh is weak."* (Patient 9, female, aged 68)

According to patients' statements, concrete types of exercise or other possibilities were not mentioned, directions were mostly quite vague. Asked about reasons for failure regarding their own physical activity, the patients mentioned pain, lack of knowledge regarding respective offers, lack of mobility and a lack of motivation. Indeed, most of the interviewed GPs stated that they did not inform patients about self-help groups or about offers on community level for instance. Reasons for this were a lack of information and frustration about the impact of this information: the GPs who had experience in giving this information complained that a lot of patients always find excuses not to participate in these services such as the distance from their homes to the location, etc. Contrary to these statements, patients welcomed basic information on self-help groups, but they were often unsure about possible

benefits and also expressed their reservations, in particular regarding availability or location in the rural environment. Receiving just a short, vague hint without a clear advice or motivation was regarded as insufficient.

Suggestions concerning improvement of care

The interviewed GPs were convinced that a gate keeper role for GPs as in many other health care systems could reduce patients' pressure to refer to orthopaedics and decrease performed X-rays. Some GPs mentioned that better communication with specialists could increase efficacy of treatment, but no specific suggestions how to achieve this were made. Many GPs stated that the payment system has to be changed in order to upgrade conservative treatments and conversations with the patient. Due to the insecurity regarding NSAIDS, some GPs also desired evidence-based pharmacological recommendations. Interestingly, patients could define their needs of care, but ideas for improvement were quite vague such as better communication, etc.

For most GPs an involvement of practice nurses -which is currently only marginally the case in Germany- is imaginable in the area of lifestyle counselling and advice giving. Involvement in the diagnostic process was refused. Main barriers mentioned were lack of professional knowledge and lack of time due to administrative overload.

Moreover, all GPs stated that interventions performed by practice nurses have to be reinsured sufficiently. Interestingly, practice nurses' opinions were quite similar to GPs' statements: they mentioned lack of knowledge due to professional education which is mainly focused on administrative issues. Especially younger practice nurses desired more involvement. They regarded this as an upgrade of their profession. Some of the nurses declared that they would like to offer links to self-help groups or sport groups if this information would be available in the practice.

To receive information and advice from practices nurses – by printed information or lectures – was acceptable for most patients. But some of them indicated – as some GPs did – that they fear a worsening of the trustful doctor-patient-relationship if the nurse is involved in too many proceedings. However, missing information about offers, e.g., in the community caused statements as the following one:

> *"There is a "Nordic walking group" in town...I know that some of our patients participate, but I really don't know to whom I should send the patients to."* (Practice nurse 7, aged 29)

Table 4. Suggestions concerning improvement of care

General Practitioners	Patients	Practice Nurses
Ideas how to improve treatment (19):	***Whishes concerning GP (16):***	***Team approach (20):***
Gate keeper role for GP (14)	Transparency concerning normal course of disease (11)	Imaginable (15)
Financial reward for communication/more time for conversation (11)	Using less medical terms (3)	Not imaginable (5)
Evidence based pharmacological recommendations (5)	GP should more openly address psychological complaints, direct questions about mood (3)	***Possible tasks for practice nurses in the context of a team approach (15):***
Improved cooperation with orthopaedics (5)	More time (1)	Talking to the patient (9)
Integrating the patients' social system (e.g. family) into treatment (2)	***Team approach (20):***	Counselling in groups (2)
More openly address psychological complaints of the patients (1)	Imaginable (13)	Asking patient about reason for consultation (2)
Team approach (20):	Not imaginable (7)	Calling the patient in regular intervals and ask about pain, side effect of medications (2)
Imaginable (18)	***Possible tasks for practice nurses in the context of a team approach (10):***	Motivating the patient to use self-help groups and social contacts (2)
Not imaginable (2)	Informing the patient about additional (non-pharmacological) approaches (9)	Organising self-help groups (2)
Possible tasks for practice nurses (20):	Informing about offers on the community level, sport groups, self help groups (7)	Exchanging information about the patient with the GP (2)
Information about offers on the community level/self help groups (11)	Asking for side effects (5)	
Providing additional written information (8)	Asking patient about his mood (4)	
Relaxation techniques (2)	Talking to the patient sympathetically (3)	

Discussion

In addressing different areas of OA treatment our study provides several important findings: the main finding is that although patients with osteoarthritis report on pain and disability as a primary concern, they do not feel that these topics are adequately addressed by their GP or specialty physician. Former studies also revealed a strong desire of OA patients for more information, but it remained unclear what kind of information was mainly required[23]. The qualitative approach of this study helped to specify the patient's needs, which are clearly focused on the individual perspectives regarding pain and mobility rather than on information about the pathology of the disease.

Regarding diagnosis and handling of OA, statements of GPs are concordant with previous studies showing that GPs have developed individual approaches to the management of OA. They perceived no major problems in diagnosing OA but had [24,25] difficulties in assessing concomitant depression. Possible implications for practice could be to provide easy-to-use and less time consuming screening tools for depression such as, e.g., the PHQ-9. Moreover, most GPs seem to be aware that OA in primary care is mainly a syndrome and that X-rays contribute less to the management but may label the patient as chronically ill. As Bedson et al. discussed, this approach may be inadequate in primary care[26]. But many GPs felt

urged by patients to perform referrals, and consequently the wish for a gate keeper role – which was assumed to reduce this pressure – was frequently mentioned.
In accordance with former research, NSAIDs represented the most important treatment for the interviewed GPs, but also an important source of uncertainty on both sides. Furthermore, ineffective pain treatment is still an important problem on both sides[27-29].
Since Paracetamol is known to be as effective as NSAIDs for mild and moderate OA but associated with fewer side effects than NSAIDs, our findings suggest that GPs' awareness about this fact needs to be increased. They should also communicate this to their patients. But also if NSAIDs or opiates are required, positive effects of NSAIDs and opiates and importance of pain control for physical ability instead of arguing about side effects could lead to a more appropriate pain treatment.
GPs considered their impact on lifestyle of patients as low and were quite frustrated about behavioural interventions. Appropriate motivation strategies and lectures on adequate sport for patients could be possible interventions. Ideally, these educational activities are connected with a linkage to local patient groups and community offers. The practice nurse could provide advice to individual patients or groups of patients (similar to the already existing sessions with diabetes patients), provide follow-up by telephone to support behaviour change in patients and provide information on community support. All these options imply new roles of the practice nurse in Germany, so evaluations to test the feasibility and effectiveness of these roles are recommended.
GPs desired a gate keeper role to decrease patients' pressure for extensive diagnostic procedures and referrals. Involvement of practice nurses were considered reasonable in advice giving and lifestyle counselling.
Our study was probably the first to simultaneously examine the perspectives of primary care physicians, patients and practice nurses on the management of osteoarthritis simultaneously. We noticed that patients in our study were relatively old. Older people tend to be happier with the health care they receive[30,31]. On the other hand, our study sample was consistent with the real patient population suffering from osteoarthritis in primary care. Nevertheless, some limitations have to be considered. The aim of qualitative research is to generate ideas and hypotheses. Due to the methodological approach and the sample size, quantitative conclusions can not be drawn. It is also important to recognise that the statements reflect individual opinions, and that e.g. self-reported behaviour must not correctly reflect the real behaviour or does not reflect reality. For instance, if GPs report they

have no problem in distinguishing articular form periarticular pain this does not mean that they are correct in doing so. Additionally, the German system of care of people suffering from musculoskeletal disorders may be unique in the world due to the high amount of non-surgical orthopaedic physicians working in practices and representing some kind of midlevel structure between primary care and the orthopaedic surgeon located at hospitals. Problems arising from this situation, as for instance the high frequency of performed referrals and X-rays, cannot easily be transferred to different health care systems.

Conclusion

Osteoarthritis is a disease which will become increasingly visible in years to come. In search of practical and simple interventions on a primary care level this study resulted in a series of valuable suggestions about what patients require and how a practice team can respond: GPs should focus more on disability and pain and on giving information about treatment since these topics are often inadequately addressed. Advanced approaches are needed to increase GPs' impact on patients' lifestyle. Being aware of the problem of labelling patients as chronically ill, a more proactive, patient-centred care is needed.

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Chapter 2a

Cultural adaptation and validation of a German version of the Arthritis Impact Measurement Scales (AIMS2)

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Abstract

Objective: To validate a translated and culturally adapted version of the Arthritis Impact Measurement Scale (AIMS) 2 in primary care patients with osteoarthritis (OA) of the hip and knee.

Method: The AIMS2 was translated into German and culturally adapted. The questionnaire was then administered to 220 primary care patients with OA of the knee or hip. 209 questionnaires were returned and analysed. Test-retest reliability was tested in 50 randomly selected patients: of these 42 completed the questionnaire for a second time after two weeks.

Results: Item-scale correlations were reasonably good as well as the discriminative power of separate scales. The assessment of internal consistency reliability also revealed satisfactory values; Cronbach's alpha was 0.77 or higher for all scales. The test-retest reliability, estimated in an intraclass correlation coefficient (ICC), exceeded 0.90, except the "social activities" scale (0.87). Since only patients with OA of the lower limb were enrolled, substantial floor effects occurred in the "arm function" (28.2%) and the "hand and finger function" scale (29.2%). The principal factor analysis confirmed the postulated three-factor structure with a physical, physiological and social dimension, explaining 48.5%, 13.9% and 6.8% of the variation, respectively. External validity was assessed by calculating correlations to the Western Ontario and MacMaster (WOMAC) osteoarthritis questionnaire a pain visual analogue scale (VAS) and the Kellgren score as well as to disease duration. Spearman's "R" achieved satisfactory values for the corresponding WOMAC scales and the pain-VAS. Correlations with disease duration as well as with the radiological grading were low.

Conclusion: The GERMAN-AIMS2 is a reliable and valid instrument to assess the quality of life (QoL) in primary care patients suffering from OA.

Background

Osteoarthritis (OA) is the most common joint affection worldwide[1]. According to estimates of the World Health Organization (WHO), 190 million people worldwide are suffering from symptomatic OA. It is frequently associated with pain und functional impairment. In recent years, health-related quality of life (HRQL) has increasingly become an important outcome measure in clinical trials and treatment. The Arthritis Impact Measurement Scale (AIMS), developed by Meenan et al. in 1980 for rheumatoid arthritis, was one of the first self-administered questionnaires to assess functional status and HRQL[2]. In 1992 the AIMS2, a revised version of the original version of AIMS, was released. In many validation studies it has proven to be a practical, reliable and valid instrument in clinical research and also in clinical practice[3-5]. Today the AIMS2 is one of the most commonly used instruments to assess HRQL. With the AIMS2-SF, Guillemin et al. developed a less time consuming version[6-8]; but, nevertheless, the original long version, the AIMS2, remains the most important tool in assessing HRQL of arthritis patients. Mostly, the AIMS2 was used in a hospital setting, but results from clinical research cannot simply be transferred to a primary care setting. Furthermore, it can be assumed that acceptance of time-consuming tools may be lower than in a hospital setting. Additionally, assessment instruments cannot just be translated, since cultural differences do interfere with reliability and validity. Although about 140 million people in the world speak German and it is one of the most frequent languages in Europe, a German version of the AIMS2 was not yet available. The aim of our study was to translate the AIMS2, assess cultural relevance by an expert panel and finally validate a culturally adapted version of the AIMS2 in primary care patients with OA of the knee or hip.

Subjects and methods

Recruitment of patients

From April to July 2006, 220 patients were recruited consecutively in 20 primary care practices in Germany. The practices were randomly selected from the 75 practices in the PraxArt project. This project aims to improve the quality of life (QoL) of patients with OA in primary care. It is financed by the German Ministry for Education and Research over a period of 6 years and will assess the effects of a multifaceted intervention in a large randomised controlled trial with over 2000 patients. Inclusion criteria were at least 18 years of age, meeting the criteria of OA according to the American College of Rheumatology (ACR)[9,10] and sufficient German language skills to understand and answer the questionnaire. Furthermore,

a diagnose-specific X-ray, performed within the 6 months prior to questionnaire completion, was required. To exclude patients with a doubtful OA diagnosis, a score according to Kellgren and Lawrence of at least 2 was required[11]. Patients were addressed in consecutive order. General practitioners (GPs) created a list with all addressed patients. This enabled linkage of the questionnaires with the medical file to compare nonrespondents with patients who returned the questionnaires. All patients gave their informed consent to the study, which was approved by the ethics committee of the University of Heidelberg. They were informed that the GP did not get knowledge about the answers and that the information from the medical file was given to the university anonymously. Patients received the AIMS2 together with a short information about the aim of the study. They were asked to personally complete the questionnaire. After 2 weeks, follow-up questionnaires were sent by mail to a subset of 50 patients together with a note explaining that the follow-up was not meant to remember the initial replies, but to complete the questionnaire according to the present situation.

Translation and cultural adaptation

The translation process was performed according to the recommendations for the cross-cultural adaptation of HRQL measures[12]. In a first step, the AIMS2 was translated into German by three native German speakers. These three - slightly different - translations were discussed by an expert panel of three GPs, two orthopaedics and one rheumatologist, aiming at assessing the relevance as well as the acceptability of the items in Germany. The resulting final German version was translated back into English by a native English speaking colleague and compared with the English original to confirm that the meaning of the original version was met[12]. Slight adaptations were necessary for items 7 and 9, since the term "blocks" is no common expression of a distance in Germany. It was replaced by "a few hundred meters". Item 75, referring to the racial background had to be adapted as well. We changed the categories into "European", "Asian", and "other", since these were the only relevant ethnic groups. Regarding item 77, which refers to the school education, we categorised: less than 9 years ("kein Hauptschul-abschluss"), 9 years ("Hauptschulabschluss"), high school degree ("Fach-/Abitur"), and university degree ("Fach-/Hochschulabschluss"). In Germany it is quite uncommon to ask for the income in surveys. Even though there is unlimited and free access to the German health care system, the utilisation of health care resources shows the same relationship to the social background as in other health care systems. Therefore, and to ease comparison in future research, we decided

to calculate the equivalents of income in Euros based on the US$ amount of the original AIMS2. A first draft of the translated AIMS2 was tested in 15 patients, without problems.

Other measures

In order to assess the external validity of the scales, additional data were retrieved: pain was assessed on a 100 mm visual analogue scale (VAS)[13], all patients were asked to complete the validated German version of the Western Ontario and MacMaster (WOMAC) questionnaire[14] containing five-point Likert scales similar to the AIMS2 questionnaire. As the AIMS2, these instruments asked the patient to report about the last 2 weeks prior to the assessment. The X-rays were scored by an orthopaedic according to the criteria of Kellgren and Lawrence[11].

Statistical analysis

Data were entered in Microsoft Excel spreadsheets and analysed with the SPSS statistical package (version 14.0). When necessary, items were recoded and transformed from graduated 10-point scales, Likert scales of GER MAN-AIMS2 and WOMAC and patient self-assessment so that results between 0 and 10 - with 0 representing the best health status and 10 representing the worst - were yielded for all items. In case of missing values, the respective scale could not exactly be calculated and was therefore excluded from further analysis. Descriptive analysis included mean and standard deviation (SD). Since notable floor and ceiling effects would represent some limitation, we also calculated the percentage of participants achieving the lowest and highest possible score.

To assess internal consistency reliability, we calculated Cronbach's alpha to estimate if each item of a scale is appropriate to assess the underlying concept of its scale[15,16]. In accordance with comparable studies, values above 0.7 were considered as acceptable internal consistency; values above 0.9 were regarded as high internal consistency[7,17].

As an estimate of test-retest reliability, the intraclass correlation coefficient (ICC) was used. The ICC assesses the correlation of scales at two different measure points. It was calculated based on the 12 scales named as "areas of health, impacted by arthritis". A random sample of 50 patients from the initial sample of 209 was asked to complete the questionnaire again 14 days later. In order to be eligible for retest, patients had to have no change in therapeutic regime, lifestyle or medication during those 14 days. This was confirmed by all of the 42 patients who returned their questionnaires after this period.

Scale internal validity was assessed by computing Pearson's r for the correlation of the items with the respective scales corrected for overlap to avoid the bias of self-correlation. A correlation of at least 0.4 for Pearson's r was assumed as the standard for supporting scale internal consistency[7,17]. Item-discriminant validity shows to what extent an item measures what it is not supposed to measure, the degree of discriminatory power. It was assessed by computing the correlation (Pearson's r) of each item with the other scales. In order to support high discriminatory power of scales, there should be no high correlation for item discriminance.
Convergent validity was assessed using external and internal criteria. We calculated Spearman rank correlation "R" since different systems were compared and a linear relationship could not be assumed. To confirm convergent validity, we computed Spearman's R for correlations between the GERMAN-AIMS2 scales and the scales of the previously validated WOMAC questionnaire, the pain-VAS as well as the Kellgren and Lawrence score. In this context, correlations between 0.40 and 0.60 were regarded as good correlations and values above 0.6 as very high correlations[18]. P-values are provided in order to show levels of statistical significance.

Construct validity
To explore construct validity, we conducted a principal component factor analysis with varimax rotation analysis. This procedure reveals factors that explain variation of the specific scale. If the factor loading is in accordance with the hypothetic construct assumed to underline the specific scale, construct validity can be confirmed. The criterion for factor extraction was an eigenvalue >1.0.

Results

The GPs addressed 220 patients in total, 11 of them denied completing the questionnaire; the main reason given was time effort. Regarding age and disease duration, responders and nonrespondents did not differ significantly. Table 1 displays the baseline characteristics of the 209 patients who returned the questionnaires. Men were overrepresented in the patient group with OA of the hip (43/72); in contrast, in the knee group nearly two-thirds (89/137) were women. Mean duration of disease was 7.9 (SD 6.8) years. 128 patients were at least working part-time; for the retired persons the "work" scale could not be calculated, which has to be considered in the upcoming analyses.

Table 1. Baseline-characteristics of the 209 enrolled patients

	Mean	SD/%
Age (years)	57.3	9.3
Female	134	64.4%
Duration of disease (years)	7.9	6.8
Retired form work	138	66.0%
Main manifestation of OA		
Hip	72	34.5%
Knee	137	65.5%
WOMAC		
Pain	12.9	4.7
Stiffness	4.6	1.9
Function	44.1	11.7
VAS pain	51.8	19.4
Kellgren score	2.62	0.85

The descriptive statistics of the individual scales are displayed in table 2: mean, SD, percentage of people achieving the lowest scores (indicating best health) and patients achieving the highest scores (indicating worst health status).

Table 2. Score distribution and response rates of the AIMS2

	Response rate (%)	Mean (0-10)	SD	Ceiling (%)	Floor (%)
Mobility level	92	3.8	2.3	0.9	0
Walking and bending	93	4.3	2.4	0	0
Hand and finger function	91	0.9	2.3	0	29.2
Arm function	92	1.4	2.7	0	28.2
Self care	97	1.6	2.2	0	0
Household tasks	92	1.7	2.4	0	0
Social activities	99	4.9	2.0	0	0
Support from family and friends	100	2.4	2.7	0	0
Arthritis pain	97	5.5	2.7	0	0
Work*	93	2.8	2.3	0	0
Level of tension	92	4.9	1.7	0	0
Mood	94	4.3	1.5	0	0

* The percentage refers to a number of 128 patients who were not retired.

Notable floor effects occurred in the scales addressing limitations to the upper limb, "arm function" (29.2%) and "hand and finger function" (28.2%), indicating nearly one third of the patients had no notable limitation of the upper limb. This finding is mainly due to the study sample that consisted of patients with OA of the hip or knee. Notable ceiling or floor effects did not occur in any other scale. The response rate indicates in how many of the received questionnaires all items of the specific scale were completely answered. As can be seen, the response rate was over 90% in all scales. Interestingly, the highest values were achieved in the scales referring to the social situation.

Assessing scale internal validity and reliability

Table 3 shows the statistical calculations of scale internal validity and reliability of the AIMS2. Regarding the scale internal consistency, the computed correlations of single items with the referring scale indicated high scale internal validity while surpassing the demanded minimum threshold of 0.40. Regarding the discriminatory power, Pearson's r for correlations between the items of a scale and the other scales was less than 0.4, except for some overlaps between "walking and bending" and "mobility level" and "level of tension" and "mood", as well as between "support from family and friends" and "social activities". Altogether, the values indicated high discriminatory power of scales and little redundancy.

The lowest values for Cronbach's alpha were achieved in the social activities and work scale, but all scales surpassed 0.7, most of them surpassed 0.8. This confirms high internal consistency of the scales. As an estimate for test-retest reliability, the ICC was calculated. The ICC was equal or surpassed 0.9 for all scales, except the social activities scale that achieved an ICC of 0.87.

Table 3. Parameter of scale internal validity and reliability

	Item-scale correlation	Item-discriminant validity	Reliability (Cronbach's alpha)	Test-retest-correlation (ICC)
Mobility level	0.63-0.91	0.05-0.45	0.81	0.95
Walking and bending	0.53-0.92	0.04-0.61	0.77	0.94
Hand and finger function	0.69-0.91	0.11-0.32	0.82	0.92
Arm function	0.54-0.95	0.13-0.34	0.79	0.90
Self care	0.51-0.90	0.08-0.35	0.88	0.92
Household tasks	0.63-0.92	0.04-0.38	0.83	0.94
Social activities	0.53-0.93	0.04-0.55	0.73	0.87
Support from family and friends	0.68-0.94	0.12-0.55	0.83	0.92
Arthritis pain	0.65-0.89	0.04-0.40	0.80	0.94
Work	0.53-0.92	0.09-0.38	0.75	0.93
Level of tension	0.58-0.91	0.08-0.38	0.79	0.90
Mood	0.57-0.93	0.11-0.32	0.77	0.92

Table 4 displays the results of the varimax rotation analysis for the different scales of the AIMS2. Three latent factors could be extracted. The factors "physical", "psychological", and "social" explained 48.5%, 13.9% and 6.8% of the cumulated variation, respectively. Together these three factors explained 69.2% of the variance of the questionnaire. We also calculated the factor loadings for every single item. Even though some single items loaded notably (>0.5) on two factors, for instance. some of the items referring to the "arthritis pain" scale also loaded on the psychosocial factor: the scales into which the specific items were grouped are clearly distinguished, as the high loadings of the scales indicated.

Table 4. Principal components factor analysis with varimax rotation analysis (eigenvalue > 1)

	Physical	Psychological	Social
Explaining % of variance	48.5	13.9	6.8
Mobility level	0.74		
Walking and bending	0.68		
Hand and finger function	0.62		
Arm function	0.61		
Self care	0.75		
Household tasks	0.77		
Social activities		0.58	
Support from family and friends		0.57	
Arthritis pain			0.69
Work	0.57		
Level of tension		0.77	
Mood		0.69	

Factor loadings > 0.50 are reported.

Assessing external validity

The correlations between AIMS2 scores and the data that were collected for estimating external validity are shown in table 5. We computed Spearman's coefficient R for rank correlations since different systems without linear relationship were compared. The highest correlations of the GERMAN-AIMS2 were found between the "arthritis pain" scale and both the pain-VAS (R=0.63) and the WOMAC scale for pain (R=0.61). The WOMAC questionnaire addresses only the lower limb; therefore notable correlations could only be expected with the AIMS2 scales that also addressed the lower limb. This was confirmed with the values for the correlations of WOMAC stiffness and function and the AIMS2 scales "mobility level", "walking and bending" that surpassed an R of 0.4.

Table 5. Convergent validity results: correlations between AIMS2-SF scales and external assessments (Spearman rank coefficient R)

	WOMAC			Disease	Kellgren-	VAS
	Pain	Stiffness	Function	duration	score	"pain"
Mobility level	0.43**	0.18	0.42**	0.15	0.29	0.41*
Walking and bending	0.44**	0.19	0.44**	0.23	0.37*	0.43**
Hand and finger function	0.15	0.14	0.19	0.04	0.11	0.09
Arm function	0.25	0.08	0.32	0.2	0.14	0.19
Self care	0.17	0.02	0.13	0.9	0.15	0.11
Household tasks	0.34*	-0.01	0.30	0.12	0.14	0.22
Social activities	0.08	0.05	0.80	0.13	0.09	0.02
Support from family and friends	0.05	0.23*	0.39	0.02	-0.05	0.04
Arthritis pain	0.61	0.24*	0.35	0.19	0.20	0.63**
Work	0.33	0.09	0.23	0.07	0.11	0.39*
Level of tension	0.12	0.10	0.17	0.08	0.03	0.07
Mood	0.25*	0.12	0.32	0.09	0.09	0.09

Level of statistical significance: ** < 0.01; * < 0.05

Interestingly the correlation of the WOMAC function scale and "household tasks" was also significant with an R of 0.34. In accordance with prior studies, the correlations between AIMS2 and the radiological Kellgren and Lawrence scores were low, achieving the highest value in the "walking and bending" scale (R=0.37). No other correlations with the Kellgren score were significant. Interestingly, correlations between the duration of the disease and all scales were low and did not achieve any significance.

Discussion

QoL has become an important outcome measure in clinical trials as well as in clinical practice. The internationally well-known AIMS2 is one of the most important assessment instruments for QoL of patients suffering from rheumatoid arthritis as well as OA. So far, this instrument was not available in German. As our validation study proved, validity and reliability of the culturally adapted German version is quite similar to the original version of the AIMS2.

If assessment instruments are provided in a different cultural setting, adaptations are indispensable to increase acceptability and to reduce missing data. As our study showed, the slight changes that were made according to the suggestions of the expert panel resulted in high acceptance. The fact that nearly all patients returned the questionnaire was most likely caused by the fact that they were directly addressed by their GP. The response rates regarding the different scales were quite similar to the ones reported by Arkela-Kautiainen et al. who validated the Finnish AIMS2 among patients with rheumatoid arthritis in a hospital setting[19]. The authors of the Turkish validation study even reported that all of the 141 enrolled patients answered the AIMS2 completely[20]. Nevertheless, our results suggest that the AIMS is applicable in a primary care setting where response rates are often lower than in a hospital setting.

Substantial ceiling affects occurred only in the dimensions reflecting affection of the upper limb. This finding may not represent a notable limitation since this finding is most probably due to the study sample that consisted of patients suffering from OA of the lower limb. The measures to assess the discriminative power and the scale internal consistency by computing the correlations of the scales with the other scales were satisfactory and higher than in the short version[21].

Regarding reliability, Cronbach’s alpha achieved very satisfactory results. The values for ICC in order to assess test-retest reliability indicated good reproducibility. The lowest ICC value was found in the scales dominated by

psychosocial factors. This effect already occurred in the validation of the short form as well as in validation studies in other languages[8,17].

Regarding the correlations of the GERMAN-AIMS2 scales with corresponding scales from the German WOMAC and the pain-VAS, it has to be acknowledged that we only included patients with OA of the lower limb. But the fact that high correlations between the pain-VAS and the corresponding AIMS2 scales as well as to the scales that were affected by OA could be observed, confirmed the underlying construct of the ‘‘arthritis pain’’ scale of the AIMS2. Prior studies have shown that the correlation between structural damages, reflected in X-rays, and patients’ complaints is weak[22]. This was confirmed by the weak association found between the Kellgren grading and the AIMS scales, a finding that also occurred in other validation studies of the AIMS2[20].

The principal factor analysis revealed three latent factors that can be determined as "physical", "psychological" and "social". Altogether they explain 69.2% of the variance of the entire questionnaire and indicate high construct validity. Similar findings were made in prior validation studies[5,17].

Some weaknesses of the validation study have to be considered. First of all, we were not able to assess sensitivity change, but this will be the aim of future research. The results regarding the upper limb confirmed the convergent validity of the AIMS2 since our patients had no affection of the upper limb. Due to the low values achieved in the respective scales, we cannot conclude anything about performance of these scales in relation to external criteria. Nevertheless, this study represents a structured and carefully conducted approach to validate the AIMS2 in a large sample of OA patients in primary care.

The WHO has proclaimed the current decade to be the "bone and joint decade" since the prevalence of OA is expected to rise tremendously in upcoming years[1]. OA is the most frequent affection of joint worldwide and associated with substantial impact on patients' QoL. Since researchers as well as clinicians focus more and more on QoL, the need for easy-to-use and valid assessment instruments is obvious. Worldwide established instruments as the AIMS2 enable comparisons between different populations as well as assessing the influence of different health care systems.

Conclusion

The German version of the well-established AIMS2 has reasonably good scale internal validity, reliability and external validity. Even though it is more comprehensive than the short form, response rates were high and did not indicate reduced acceptance among patients. We conclude that with the GERMAN-AIMS2 we provide a well-suited instrument for QoL assessment in patients suffering from OA of the knee or hip in a primary care setting.

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Chapter 2b

Evaluation and cultural adaptation of a German version of the AIMS2-SF questionnaire (German AIMS2-SF)

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Abstract

Objectives. The aim of the study was to examine the validity of a translated and culturally adapted version of the Arthritis Impact Measurement Scales 2, Short Form (AIMS2-SF), in patients suffering from osteoarthritis (OA) in primary care.
Methods. A structured procedure was used for the translation and cultural adaptation of the AIMS2-SF into German. The questionnaire was administered to 220 primary care patients with OA of the knee or hip. Test–retest reliability was tested in 35 randomly selected patients, who received the questionnaire a second time after 1 week. The physical scale of the original AIMS2-SF was divided into an 'upper body limitations' scale and a 'lower body limitations' scale.
Results. With values ranging from 0.52 to 0.97 for Pearson's r, item-scale correlations were reasonably good. The discriminative power of separate scales was also good, reflected in low values for correlation between different scales, indicating little redundancy. Only two items (13 and 15) referring to the symptom scale showed item-scale correlation of r=0.72 and r=0.67, respectively with the lower body limitation scale. The assessment of internal consistency reliability also revealed satisfactory values: Cronbach's α was ≥ 0.83 for all scales, except for the social interaction scale (0.66). The test–retest reliability, estimated as the intraclass correlation coefficient (ICC), exceeded 0.85 except for the affect scale (0.72). Substantial floor effects occurred in the upper limb scale (33.8%). Principal factor analysis confirmed the postulated three-factor structure with physical, physiological and social dimensions, explaining 49.8, 14.1 and 6.4% of the variation, respectively. The assessment of external validity revealed satisfactory correlations with the corresponding WOMAC (Western Ontario and McMaster Universities Arthrosis Index) scales. As expected, correlations with radiological grading were moderate to low. The correlation with the physician's assessment was high in the scales that were dominated by physical factors, but rather low in the areas of health, which were found to be dominated by psychological or social factors.
Conclusion. The German AIMS2-SF is a reliable and valid instrument to assess the quality of life in primary care patients suffering from OA. When addressing the different impacts of OA, the physical scale should be divided into an upper body scale and a lower body scale. The floor and ceiling effects revealed are in accordance with the disease characteristics of the study sample and do not limit the significance of the questionnaire.

Health-related quality of life is an important outcome measure in many clinical areas, including osteoarthritis (OA) of the knee or hip. Validated measuring instruments are needed to assess functional status and health-related quality of life in research and clinical practice. The AIMS questionnaire, originally developed by Meenan et al. in 1980 for rheumatoid arthritis, and the HAQ (Health Assessment Questionnaire) of James Fries were the first self-administered arthritis questionnaires[1,2]. Several validation studies confirmed that AIMS is a practical, reliable and valid instrument for health-related quality of life. In 1992 the AIMS2, a revised version of the original, long version of AIMS, was released and validated in many countries[3–5]. A short version of the AIMS2, the AIMS2-SF, was developed by Guillemin et al. and reduced to 26 items in order to reduce time and effort and to increase acceptance among patients in clinical trials. It was validated in France, Norway and the Netherlands for RA and in the USA for patients with OA[6–8]. In several comparison studies, performed by Guillemin, Haarvardsholm and Taal, it proved to be just as reliable and valid as the long version, but without achieving perfect agreement[6,8,9]. In covering the five components of physical, affect, symptom, social interaction and role, the AIMS2-SF is more comprehensive than the frequently used instruments WOMAC (Western Ontario and McMaster Universities Arthrosis Index)[10] and the Lequesne index[11]. This comprehensiveness makes AIMS particularly useful for studies and interventions that use a multimodal rather than a pharmacologically oriented approach, such as self-management education[12–14]. So far, a German version of the AIMS2-SF has not been available. The aim of our study was to examine the validity of a translated and culturally adapted version of the AIMS-SF2 in primary care patients with OA of the knee or hip.

Subjects and methods

Recruitment of patients

Between April and July 2004, 220 patients were recruited in 21 primary care practices in Germany. The University of Heidelberg has 210 associated teaching practices; the practices were randomly selected from a list of these practices. Inclusion criteria were: to be over 18 years of age; meeting criteria for OA according to the American College of Rheumatology[15,16] and sufficient German language skills to understand and answer the questionnaire. In addition, the availability of a diagnosis-specific radiograph, not older than 6 months at the date of questionnaire completion, was required. Patients were recruited in two regions with completely different dialects. All eligible patients gave their informed consent

to the study, which was approved by the ethics committee of the University of Heidelberg. Patients were handed a questionnaire together with a small amount of information about the aim of the study and were asked to complete the questionnaire personally. After 1 week, follow-up questionnaires were handed to a subset of 35 patients together with an explanatory note, saying that the follow-up was not meant to remember the initial replies (but complete the questionnaire according to the current situation). Only two patients of the 222 initially approached refused to complete the questionnaire: this because of the time and/or effort needed.

Translation and cultural adaptation

The German version of AIMS2-SF was translated and retranslated according to guidelines for cultural adaptation in order to address content validity[17]. Slight adaptations were necessary for item 7 ('Did you have problems either walking several blocks or climbing a few flights of stairs?'. The expression 'blocks' is not commonly understood in German as a measure for distance and was replaced by 'a few hundred metres'. Item 49 contains the expression 'bothered by nervousness or your nerves', which sparked intense discussion among the translators because there are various potential translations in German. The case was settled for a more understandable translation capturing the original idea of the item rather than the more direct translation.

The draft translation was piloted with 15 patients. In accordance with Taal et al., we replaced item 33 of the original AIMS2, 'How often did you go to a meeting of a church, club, team or other group?', with item 31, 'How often did you visit friends or relatives at their homes?', because this is to be expected to increase the internal consistency of the social interaction component[8,18]. On the other hand we did not follow the Bland-Altman approach, unlike Taal and Havaardsholm, who replaced item 42 of the original AIMS version, 'How often did your pain make it difficult for you to sleep?', with item 38, 'How would you describe the arthritis pain you usually had' [9,18]. Like Ren and colleagues[7], who validated the AIMS2-SF in the USA among patients with OA, we divided the German AIMS2-SF component 'physical' into the two components 'upper body limitation' and 'lower body limitation'. Ren et al. discussed some possible limitations due to ceiling and floor effects, especially in patients suffering from OA to the knee or hip. As they did, we included item 1 (drive a car or use public transport), item 11 (need help to get dressed) and item 12 (need help to get out of bed) in the lower body limitation scale. We also followed their approach in including item 24 of the AIMS2-SF, 'family and friends

sensitive to personal needs', and item 19, 'enjoy the things you do', in the affect scale and not in the social interaction scale. Contrary to Ren et al., and in agreement with some previous validation studies, we did not exclude the role component, even if this scale is usually only answered by half of the participants addressing only those who are still involved in the working process.

Other measures

In order to assess the external validity of the scales, additional data were retrieved. The patient's general practitioner (GP) was asked to evaluate the severity of arthritis based on available radiographs, the patient's history and clinical examination based on the classification criteria of the American College of Rheumatology[15,16]. The GP's evaluation was scored on a 0–10 scale, 10 representing no limitation of quality of life by arthritis and 0 representing massive limitation of quality of life. All patients were also given the validated German version of the WOMAC questionnaire[19], containing five-point Likert scales similar to the German AIMS2-SF questionnaire. For inclusion in the study, an X-ray of the affected joint, not older than 6 months, was required. The X-rays were scored according to the criteria of Kellgren and Lawrence[20]: grade 0=normal; grade 4=massive alterations with complete collapse of the joint space.

Statistical analysis

Data were entered in Microsoft Excel spreadsheets and analysed with the SPSS statistical package (version 11.0). When necessary, items were (according to the recommendations of Meenan et al.[1,3]) recoded and transformed from graduated 10-point scales, Likert scales of the German AIMS2-SF and WOMAC and patient self-assessments, so that results for all items lay between 0 and 10: 0 representing the best and 10 the worst health status. Descriptive analysis included mean and standard deviation, and in order to assess floor and ceiling effects the percentage of participants achieving the lowest and highest possible score was calculated.

INTERNAL CONSISTENCY RELIABILITY. As an indicator of internal consistency reliability, we calculated Cronbach's α to estimate whether each item of a scale is appropriate for assessing the underlying concept of its scale[21,22]. Achievable values for Cronbach's α range from 0, signifying no internal consistency, to 1, signifying identical results. We considered high internal consistency to be represented by values of 0.50–0.70 for group comparisons and by values of over 0.90 for individual patients' results.

TEST–RETEST RELIABILITY. We used the intraclass correlation coefficient (ICC) as an estimate of test–retest reliability. In order to assess the test–retest reliability of the individual scales, we computed the ICC based on Ren et al.'s six-component model of the AIMS2-SF: upper body limitation; lower body limitation; affect; symptom; social interaction; and role. A random sample of 35 patients from the initial sample of 220 was asked to complete the questionnaire again after 7 days. All of the 35 patients selected for the retest returned their questionnaires. In order to be eligible for retest, patients had to have no change in therapeutic regimen, lifestyle or medication during these 7 days.

SCALE INTERNAL VALIDITY. Scale internal validity was assessed by computing the correlation (Pearson's r) of the items with the respective scale corrected for overlap to avoid bias from selfcorrelation. A correlation of at least 0.4 was assumed as the standard for supporting scale internal consistency[7,23]. Itemdiscriminant validity shows the extent to which an item measures what it is not supposed to measure: the degree of discriminatory power. It was assessed by computing the correlation (Pearson's r) of the items with the other scales. Cut-off values have not been defined, but in order to support the high discriminatory power of scales there should not be a high correlation for item discriminance.

CONVERGENT VALIDITY. Convergent validity was assessed using external and internal criteria. In using external criteria to estimate convergent validity different systems are usually compared and a linear relationship cannot be assumed. Therefore, Spearman rank correlation tests are most commonly used, e.g. in the validation studies of Stucki et al. (WOMAC)[19], Roos et al. (WOMAC)[24], Ludwig et al. (Lequesne) [25] and Salaffi et al. (AIMS)[23]. This study challenged the hypothesis that AIMS2-SF scales correlate with corresponding scales of the previously validated WOMAC questionnaire. In addition, the correlations of the AIMS2-SF with the Kellgren score and the physician assessment were estimated by computing the Spearman rank test. As Roos et al. have discussed in this context[24], correlations usually range between 0.2 and 0.6: correlations between 0.40 and 0.60 are regarded as good correlations and values above 0.6 as very high correlations. P-values are provided in order to show levels of statistical significance.
In addition to external criteria, convergent validity was also assessed by analysing demographic subgroups by age, gender and level of education. A low level of education was defined as education only as far as secondary school. Education

more advanced than this was considered a high level of education. To compare the different groups we used Student's t-test for independent samples.

CONSTRUCT VALIDITY. To explore construct validity we conducted a principal components factor analysis with varimax rotation analysis. The criterion for factor extraction was an eigenvalue >1.0.

Results

Table 1 displays the baseline characteristics of the study sample. Women were slightly under-represented in the patient group with coxarthritis. This is in line with the epidemiology of arthritis, which shows that women suffer more from gonarthritis and men more from coxarthritis. Mean duration of disease was 11.3 yr among women and 8.8 yr among men. For subgroup analysis, data on school and professional education and present occupation were retrieved.

Table 1. Baseline-characteristics of patients

Sex	Main manifestation of OA		N	Kellgren (Mean)	S.D.	Duration Mean	S.D.	Age	S.D.
	Hip	Knee							
w	37	60	97	2.85	0.96	11.34	6.29	43.76	23.58
m	78	45	123	2.55	0.74	8.78	5.11	49.86	13.30
Total	115	105	220	2.68	0.85	9.90	5.79	47.17	18.75

Table 2 shows the descriptive statistics of the individual scales: mean, standard deviation, percentage of people achieving the lowest scores (indicating best health) and patients achieving the highest scores (indicating worst health status). As expected in a sample of patients suffering from OA of the knee or hip, the mean score on the lower body limitation scale was 3.37, clearly higher than the mean score on the upper body limitation scale (2.32). The difference in means (Student's t-test) was statistically significant ($P<0.01$). Substantial floor effects occurred in the upper body limitation scale, indicating that one-third (33.8%) of the patients had no limitation of the upper limb. Ceiling effects, representing the patients achieving the highest possible score and indicating the worst health status, were below 2.5%, except for the component lower limb function (3.9%). Substantial floor effects occurred in our study sample in the component upper body limitation (33.8%) and moderate floor effects in the role scale.

Table 2. Descriptive statistics and score distributions for GERMAN-AIMS2-SF

	N	Mean (Range 0-10)	Median	S.D.	Ceiling, %	Floor, %
Upper body limitation	219	2.32	2.02	1.71	0.0	33.8
Lower body limitation	216	3.37	2.75	2.06	3.9	0.0
Symptom	220	3.32	2.49	2.74	1.8	1.8
Affect	219	4.27	4.10	1.29	2.4	0.0
Social Interaction	218	5.11	5.01	1.94	2.3	0.1
Role	109	2.05	3.79	3.04	0.9	8.3

Assessing scale internal validity and reliability

Table 3 shows the statistical calculations of scale internal validity and reliability of the German AIMS-SF. Regarding the internal consistency scale, the correlations of single items with the referring scale ranged from 0.56 to 0.98, representing excellent consistency for the scales upper limb function, lower limb function, symptom and affect. Interestingly, the item-scale correlation achieved the highest values in the role scale. All scales achieved values above the minimum demanded threshold of 0.40; and therefore all values indicated high scale internal validity.

Table 3. Parameter of scale internal validity and reliability

	Item-scale-correlation	Item-discriminant validity	Reliability (Cronbach's alpha)	Test-retest correlation (ICC)
Upper body limitation	0.67-0.92	0.04-0.48	0.89	0.97
Lower body limitation	0.56-0.97	0.04-0.65	0.83	0.93
Symptom	0.69-0.94	0.13-0.72	0.83	0.95
Affect	0.58-0.98	0.13-0.35	0.82	0.72
Social Interaction	0.52-0.90	0.06-0.64	0.66	0.77
Role	0.80-0.95	0.05-0.07	0.89	0.85

Regarding discriminatory power, Pearson's r for correlations between the items of a scale and the other scales were less than 0.48, except in a few cases. Item 13, 'How often did you have severe pain from your OA?', and item 15, 'How often did your pain make it difficult for you to sleep?', of the symptom scale achieved a correlation of 0.72 and 0.67, respectively, with the 'lower body function' scale. Item 21, 'How often did you meet with friends or relatives', showed a correlation of r¼0.64 with the affect scale. Overall, the values achieved indicate high discriminatory power of the scales and little redundancy.

Computing Cronbach's α values revealed excellent values: all scales achieved values equal to or above 0.82, except for the social scale (0.66). In meeting and exceeding the recommended range of 0.5–0.7, the results indicated high internal consistency of the scales.

Generally high values for test–retest reliability were found for all scales except for the affect scale, for which the ICC was only 0.72, and the social interaction scale

(ICC 0.77). With values above 0.81, the areas dominated by physical factors and the role scale showed slightly higher test–retest reliability.

Table 4 shows the results of the varimax rotation analysis with the three latent factors that could be extracted. The factor 'physical' explained 49.8% of the cumulated variation, the factor 'psychological' 14.1% and the factor 'social' 6.4%. The high loading of these three factors in certain items confirms that the dimensions are clearly distinguished. All items referring to the symptom component (item 13, severe arthritis pain; item 14, morning stiffness >1 h; and item 15, pain influencing sleep) are loaded on two factors, physical as well as psychological, reflecting the complex nature of these areas of health.

Table 4. Principal components factor analysis with varimax-rotation-analysis (eigenvalue > 1)

	physical	psychological	social
Explaining % of variance	49.8	14.1	6.4
Usage of car or public transportation	0.56		
Staying in bed most of the day	0.57	0.47	
Trouble during vigorous activities	0.51		
Trouble walking a few hundred meters /climbing	0.43		
Unable to walk without assistance	0.46		
Pencil writing	0.92		
Button a shirt	0.91		
Turn a key	0.90		
Comb or brush hair	0.70		
Reach something above the head	0.69		
Need help to get dressed	0.26	0.30	
Need help to get out of bed	0.39		
Severe arthritis pain	0.31	0.81	
Morning stiffness > 1 hour	0.37	0.75	
Pain influencing sleep	0.38	0.70	
Felt tense		0.48	
Bothered by nerves		0.50	
In low or very low spirits		0.64	
Enjoying things		0.58	
Feeling to be a burden for others		0.30	
Get together with friends			0.84
Phoning close friends or relatives			0.78
Visiting friends or relatives			0.65
Family or friends sensitive to your needs			0.77

Factor loadings > 0.30 are reported

Assessing external validity

Table 5 shows the correlations between German AIMS2-SF scores and the data that were collected to estimate external validity. To compare different systems without linear relationship, we computed Spearman's rank correlation coefficient p. The highest correlation of the German AIMS2-SF was found between the symptom scale and the WOMAC scale for pain (p=0.83). The WOMAC questionnaire

addresses only the knee and hip; therefore correlations of the German AIMS2-SF lower limb function scale with the WOMAC scales ranging from 0.52 to 0.78 are higher than for the upper limb function scale, where Spearman's p ranges from 0.28 to 0.47. In accordance with previous studies, the correlations between the German AIMS2-SF and the radiological Kellgren and Lawrence scores were low, achieving the highest values in the symptom scale (p=0.42) and the lower body limitation scale (p=0.36).

Correlations between AIMS2-SF and the physician's assessment ranged from low values for the role and social interaction scales (p=0.17 and p=0.23, respectively) to good values for the lower body limitation scale (p=0.55) and the symptom scale (p=0.60).

Table 5. Convergent validity results: Correlations between AIMS2-SF scales and external assessments (Spearman rank coefficient R)

AIMS-Scale	WOMAC				Kellgren-Score	Physician assessment
	Function	Stiffness	Pain	Global		
Upper body limitation	0.28**	0.36**	0.47**	0.32 **	0.27**	0.42**
Lower body limitation	0.54**	0.52**	0.78**	0.46 **	0.36**	0.55**
Symptom	0.52**	0.56**	0.83**	0.57 **	0.42**	0.60**
Affect	0.36**	0.45**	0.58**	0.41**	0.25	0.35**
Social Interaction	0.29**	0.28**	0.41**	0.29**	0.12	0.23**
Role	-0.21*	-0.12	-0.17	0.21*	0.21*	0.17

Level of statistical significance: ** < 0.01; * < 0.05

Relationship with demographic subgroups

The use of demographic and socioeconomic subgroups is an additional approach to the assessment of convergent validity. Table 6 displays the results of these analyses. The differences were assessed with Student's t-test for independent samples. Women obtained significantly higher average scores in the physical and symptom scales, indicating worse health status and more burden due to OA. Women also had higher average scores for social interactions (5.69) and affect (4.81), with a statistically significant difference in the variance of the means (P<0.05 and P<0.01, respectively). This is in line with previous studies from Salaffi et al. and may be due to the fact that female study participants, on average, suffered longer from arthritis than male participants (11.3 vs 8.8 yr)[23].

As expected, the scores for the patients aged over 65 yr indicated a greater effect of OA in all scales, especially in the scales referring to physical aspects and pain. Similar differences could be found between the participants with a low vs high educational level. A higher educational level is associated with lesser burden from reduced physical capacity and pain, as represented in the symptom scale.

Table 6. Mean scores for demographic subgroups - Students t-test

	Sex			Age			Education		
	Female	**Male**	**P**	**< 65**	**> 65**	**P**	**Low**	**High**	**P**
N	97	123		159	60		125	95	
Upper body limitation	3.62	2.55	0.61	2.31	4.11	**	3.50	2.03	**
Lower body limitation	4.37	2.62	**	2.63	5.45	**	4.12	2.39	**
Symptom	4.69	3.09	**	2.50	5.98	**	4.49	1.88	**
Affect	4.81	3.83	*	4.01	4.95	0.47	4.55	3.90	0.64
Social interaction	5.69	4.64	**	4.82	5.88	0.43	5.44	4.66	0.71
Role	3.11 (n=35)	2.72 (n=74)	0.55	-	-	-	3.33 (n=46)	2.61 (n=63)	0.07

Level of statistical significance: ** < 0.01; * < 0.05

Discussion

In research and practice, valid measurement instruments are needed to assess quality of life in patients with OA of the knee or hip. The internationally well-known AIMS2-SF was not yet available in German. Therefore, we translated the instrument into German and tested it in a sample of primary care patients. Our findings showed that the instrument had reasonably good scale internal validity, reliability and external validity in the primary setting. It is easy to use for patients and it covers most important areas of quality of life that are influenced by degenerative joint processes. We conclude that the German AIMS2-SF is well suited for quality of life assessment in patients suffering from OA of the knee or hip in a primary care setting.

The results of the assessment of scale internal validity, internal consistency and item-discriminant validity indicated that the German AIMS2-SF questionnaire appears to measure what it is supposed to measure and that its items are selective and non-redundant.

Cronbach's α showed very satisfactory results and by following the approach of Ren et al. in including item 19 (which asked the patients whether they enjoyed the things they did) in the affect scale, even the value for the social scale reached 0.66: results quite similar to those of the validation study of Ren (0.67) and much better than in the study of Guillemin et al. (0.32) [6,7]. The ICC values (assessing test–retest reliability) indicated good reproducibility.

The lowest ICC value was found for the affect scale and the social interaction scale: an area that largely depends on external factors, such as telephone calls and visits from friends and family. These scales have performed similarly in validation studies in other languages[8,23].

Correlations of the German AIMS2-SF scales with corresponding scales from the already validated German WOMAC were very satisfactory. In achieving quite different values for the upper body limitation and lower body limitation scales, the

correlations with the WOMAC questionnaire substantiate the approach of Ren et al.[7] in dividing the physical scale into scales addressing upper and lower limb functioning. Ren et al.[7] (using a different coding, 0 representing worst and 10 representing best health status) found substantial ceiling effects in their validation study among patients with OA. They discussed possible limitations of the AIMS2-SF in applying it to patients with OA of the lower limb section. In our inclusion of patients suffering from OA to knee or hip we found no substantial ceiling effects in the lower limb scale but quite large floor effects in the upper limb section. Our results are in line with the findings of Taal et al.[8], who reported moderate floor effects (1.6) and no ceiling effects (0.0) in the physical scale, and Salaffi et al.[26], who also found only moderate ceiling (0.6–4.1) effects in the scales representing lower limb function but substantial floor effects (43.9–67.1) in the scales representing upper limb function. Like Salaffi et al., we regard the disease characteristics of the study sample as responsible for these results. To summarise, we did not find any possible limitations due to ceiling or floor effects of the German AIMS2-SF in patients suffering from OA of the knee or hip.

As expected, and supported by clinical experience, the correlation between the AIMS2-SF and radiological scores were low to moderate in the symptom and lower body limitation scales[19,27,28]. It is known that self-reported functional ability assessed by instruments such as the AIMS reflects physical impairment due to the arthritic joint disease quite well[29]. Therefore, it is not surprising that the correlation was high between physician assessment and physical aspects of the AIMS. The fact that the correlation was much lower for items reflecting social interaction may indicate that these areas are outside the scope of physicians' assessment of their patients' quality of life, even for GPs who are well acquainted with their patients, as was the case in this study. Therefore, these results reflect the potential benefit of AIMS in OA-related quality of life assessment in primary care.

As in previous validation studies, the principal factor analysis indicated high construct validity by revealing three latent factors: physical, psychological and social; these explained 70.4% of the variance of the entire questionnaire[5,23]. Comparison of demographic subgroups consistently showed plausible results: impairment increased with age[28]. In line with previous studies, educational level affected quality of life. Salaffi et al.[26] also found higher levels of education to be related to higher quality of life in the validation study of the Italian AIMS questionnaire. Therefore, the results for the demographic subgroups substantiate the convergent validity of the German AIMS2-SF.

Especially due to demographic trends, the incidence and prevalence of OA are increasing in most western industrialised nations. They cause a substantial burden of disease, as well as high direct and indirect costs. OA has a massive impact on patients' quality of life, which poses a challenge to reliable and valid measurement instruments for the assessment of potential interventions. The well-established WOMAC and Lequesne questionnaires can be used to assess medical and surgical interventions in OA. In addition to these two instruments, the AIMS2-SF questionnaire also addresses aspects of life that are less directly related to joint diseases. The AIMS2-SF is therefore suitable for use in the evaluation of multimodal interventions, such as self-management programmes[30]. Results from hospital-based studies cannot easily be generalised to primary care. The present validation study underlines that the German culturally adapted AIMS2 short version promises to have these qualities. The instrument could be used in different German regions with distinct dialects. As in previous studies, willingness to participate was high among OA patients. This was reflected by high response rates, both in the test and the retest, and in the low rate of unanswered items.

The results presented are particularly interesting because results of hospital- or treatment centre-based studies cannot easily be transferred to a primary care setting. The results of this validation study indicate that the German AIMS2-SF is a valid and reliable instrument for assessing the quality of life of patients with OA, and it provides us with an important instrument to assess the effects of complex interventions in primary care.

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Chapter 3

Comparison of AIMS2-SF, WOMAC, X-ray and a global physician assessment in order to approach quality of life in patients suffering from osteoarthritis

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Abstract

Background: Chronic diseases like osteoarthritis (OA) substantially affect different dimensions of quality of life (QoL). The aim of the study was to reveal possible factors which mainly influence general practitioners' (GPs') assessment of patients' QoL.

Methods: 220 primary care patients with OA of the knee or the hip treated by their general practitioner for at least one year were included. All GPs were asked to assess patients' QoL based on the patients' history, actual examination and existing X-rays by means of a visual analog scale (VAS scale), resulting in values ranging from 0 to 10. Patients were asked to complete the McMaster Universities Osteoarthritis Index (WOMAC) and the Arthritis Impact Measurement Scale2 Short Form (AIMS2-SF) questionnaire.

Results: Significant correlations were revealed between "GP assessment" and the AIMS2-SF scales "physical" (rho = 0.495) and "symptom" (rho = 0.598) as well as to the "pain" scale of the WOMAC (rho = 0.557). A multivariate ordinal regression analysis revealed only the AIMS2-SF "symptom" scale (coefficient beta = 0.2588; p = 0.0267) and the X-ray grading according to Kellgren and Lawrence as significant influence variables (beta = 0.6395; p = 0.0004).

Conclusion: The results of the present study suggest that physicians' assessment of patients' QoL is mainly dominated by physical factors, namely pain and severity of x-ray findings. Our results suggest that socioeconomic and psychosocial factors, which are known to have substantial impact on QoL, are underestimated or missed. Moreover, the overestimation of X-ray findings, which are known to be less correlated to QoL, may cause over-treatment while important and promising targets to increase patients' QoL are missed.

Background

About 10% of men and 18% of women 60 year and older suffer from symptomatic osteoarthritis (OA)[1]. Among people aged 75 or older it is the third most common reason to visit a primary care physician[2]. Due to an increasing life-expectancy as well as a constant increase in the body mass index (BMI), which constitutes a principal risk factor for OA[3], the incidence of OA is expected to rise in upcoming years[4].

Usually, the general practitioner (GP) is not only the first care provider but also sees the patient regularly during the course of disease[5]. Moreover, the GP is the physician who is most familiar with the social background of the patients. These socio-economic and psychosocial factors contribute substantially to the quality of life (QoL) of patients[6-8]. It is known that the treatment plans of GPs and specialists are quite similar, but also that there is a broad range of possible approaches to the disease by GPs[2,5,9]. However, previous findings indicate that GPs as well as specialists seem to have a perspective that is dominated by physical aspects of OA. Psychosocial aspects and their influence on QoL seem to be underestimated[10]. Moreover, it is known that radiographic changes and subjective complaints show very poor correlation; therefore it could be assumed that their contribution to physicians' assessment of patients QoL may be limited. However, the extent to which psychosocial and radiological findings influence GPs assessment remains unclear. Interestingly, QoL is coming more and more into the focus of health care professionals and represents an increasingly important outcome parameter in many clinical trials[11]. Different questionnaires have been developed and validated to assess the impact of joint diseases on QoL. Assessing QoL in patients suffering from OA the most frequently used instruments are the McMaster Universities Osteoarthritis Index (WOMAC)[12,13], the Arthritis Impact Measurement Scale (AIMS)[14,15] and the Lequesne-Index[16].

WOMAC and Lequesne-Index both focus on physical effects of arthritis on mobility and physical activity and are limited to the lower limbs (hip and knee). The AIMS questionnaire originally developed by Meenan et al. in 1980 for rheumatoid arthritis is a more comprehensive tool, which includes in 78 items the five dimensions physical, affect, symptom, social interaction and role[14]. In 1997, Guillemin et al. developed a shorter version, the AIMS2-SF, containing 26 items, to reduce time effort and to increase acceptance among patients. In several validation studies the AIMS2-SF, which has recently become available in a German version [20], has proven to be a reliable and valid instrument to asses QoL of patients with rheumatoid arthritis and OA [17-19]. Due to its comprehensiveness the AIMS2-SF

gives insight into different dimensions of QoL in OA.
The aim of our study was to examine which dimensions of QoL of osteoarthritis patients are considered by GPs. To reveal factors influencing GPs' picture of patients QoL we estimated relationship to different assessment tools, AIMS2-SF, WOMAC and X-ray.

Methods

Recruitment of patients

The study was approved by the ethics committee of the University of Heidelberg. From April to July 2004, 222 patients were approached in 21 primary care practices. Inclusion criteria for patients were: aged over 18, meeting the criteria of OA according to the America College of Rheumatology (ACR) [21,22] and sufficient German language skills to understand and answer the questionnaire. All patients had to be treated by the physician for at least one year. Additionally, the availability of a diagnose-specific radiograph, not older than six months at the date of questionnaire completion, was required. In all participating practices the patients were identified by ICD-10 codes in patient files and put on a list in alphabetical order. Patients from this list were contacted in consecutive order of appearance in the practice and informed about the option to participate in the survey. After giving their written informed consent they received the questionnaire and an envelope. The enveloped questionnaires were returned in a sealed box at the practices. Neither the GP nor the practice team had any possibility to see patients' answers.
Two of the addressed patients refused to complete the questionnaires due to time effort, so that 220 patients could finally be included. Enrolled patients received the validated German version of the WOMAC and AIMS2-SF questionnaire, each containing 5 point-Likert scales. In addition, patients received short written information about the aim of the study and were asked to personally complete the questionnaire without any assistance. For subgroup analysis data on school and professional education and present occupation were retrieved.
The patient's GP was asked to evaluate the severity of arthritis based on available radiographs, the patient's history and clinical examination based on classification criteria of the American College of Rheumatology. The GP's evaluation was scored on a visual analogue scale. The scale was organized in that manner that the results achieved ordinal values with 10 representing no limitation of QoL by arthritis to 0 with massive limitation of QoL. The X-rays were scored according to the criteria of Kellgren and Lawrence[13], Grade 0 = normal and Grade 4=massive alterations with close to complete reduction of the joint space. If only one joint was

affected, the score for this joint was used. If different joints were affected, patients' highest radiological score was used.

Statistical analysis

Data were analysed with the SPSS statistical package (version 12.0). In a standardisation process, the items of AIMS and WOMAC were recoded and transformed, so that results between 0 and 10 were yielded for all items with 10 representing the best health status and 0 representing the worst. This standardisation process was performed according to the recommendations of Guillemin (AIMS2-SF) and Bellamy (WOMAC), respectively. The radiological grading according to Kellgren and Lawrence was not adjusted. Descriptive analysis included mean and standard deviation separated for the mainly affected joint (hip or knee). In order to assess floor and ceiling effects the percentages of participants achieving the lowest and highest possible score were calculated.

Group comparisons were adjusted for sex and age and, in case of ANOVA, post hoc corrections according to Bonferoni were performed to avoid effects caused by multiple testing.

As a first estimation of factors influencing GPs' assessment of patients' QoL, we computed correlations of sociodemographic variables, AIMS2-SF, WOMAC and Kellgren-score with the GP score. The correlations of the individual scales with the overall scores were computed via Spearman rang correlation. P-values are provided in order to show levels of statistical significance.

In order to identify factors independently associated with GP ratings of patient quality of life, we additionally performed a polytomous ordinal logistic regression analysis[23]. The purpose of this procedure is to model the dependence of an ordinal categorical response variable (here: GP ratings of patient quality of life) on a set of discrete and/or continuous variables (here: age, gender, education, physical, affect, symptoms, social interaction, function, stiffness, pain, Kellgren score).

Subgroup analysis

Finally, subgroup analyses were performed by age, gender and level of education. A low level of education was defined by secondary school. More advanced degrees were considered as higher education. For the subgroup analysis the Student-t-Test for independent samples was used.

Results

Table 1 reflects the baseline characteristics of the study sample, separated by gender. Main manifestation of OA in women was knee (60), while only 37 suffered mainly from OA of the hip. 78 men suffered mainly from OA of the hip, while in 45 cases men were mainly affected at the knee. This is in line with arthritis epidemiology showing that women suffer more from gonarthritis and men more from coxarthritis. Mean duration of disease among women was 11.3 years and 8.8 years among men. This difference was significant as well as the difference in age: men were older (49.8 vs. 43.7 years; $p < 0.01$).

Table 1. Baseline-characteristics of patients separated by sex

Sex	Mainly affected joint		N	Kellgren (Mean)	S.D.	Duration Mean	S.D.	Age	S.D.
	Hip	Knee							
w	37	60	97	2.85*	0.96	11.34**	6.29	43.76**	23.58
m	78	45	123	2.55*	0.74	8.78**	5.11	49.86**	13.30
Total	115	105	220	2.68	0.85	9.90	5.79	47.17	18.75

Level of significance (t-test for group comparison):*p<0.05;**p<0.01)

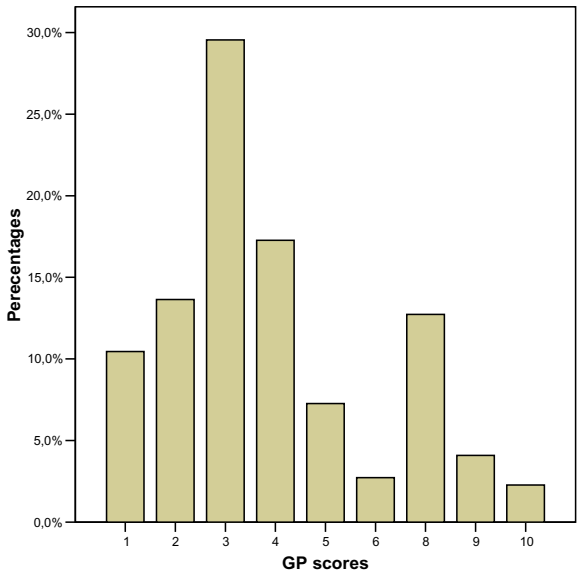
Table 2 shows the distribution of the Kellgren and Lawrence score according to the affected joint. ANOVA adjusted for age and gender with post hoc Bonferoni correction revealed no significant differences in Kellgren scores between patients suffering from osteoarthritis of hip or knee. Figure 1 shows the distribution of the GP scores in percentages.

Table 2. Kellgren Score distribution according to joint

	Kellgren-Score				
	1	2	3	4	
Hip	8	31	56	20	115
Knee	11	38	39	17	105
Total	19	69	95	37	220

*Adjusted ANOVAs (gender, age) revealed no significant differences

Figure 1.



In table 3 the characteristics of the study sample are separated by the affected joint. Differences were assessed by adjusted ANOVA: Patients suffering from OA to the knee had a significantly higher BMI (27.9 vs. 26.3; $p < 0.05$; adjusted for sex and age), and suffered longer from the joint affection (11.2 vs. 9.3 years; $p < 0.01$; adjusted for sex and age). Regarding age, the hip and the knee group did not differ (ANOVA adjusted for sex).

Table 3. Descriptive statistics and score distributions for the different assessments according to affected joint

	Affected joint	Range	N	Mean	SD
Age	Hip	38-89	115	56.53	12.39
	Knee	25-83	105	58.54	12.02
BMI*	Hip	20.3-39.7	115	26.35	3.49
	Knee	19.6-41.1	105	27.95	4.82
Duration of OA**	Hip	1-23	115	9.39	4.56
	Knee	1-24	105	11.27	5.91

Level of significance: *p<0.05; **p<0.01

Table 4 displays the descriptive statistics of the different assessments separated by the affected joint. As can be seen, the GP score as well as the Kellgren score did not differ significantly from each other. Regarding the AIMS2-SF, significant differences did occur in the scale "physical", in which a mean of 3.95 for the knee group indicated more limitation regarding physical aspects. The "symptom" scale indicated more impact due to pain in the knee group (p=0.03). "Affect", "social" and "role" did not differ significantly. In accordance to this finding the WOMAC "pain" scale revealed significantly (p=0.01) higher results for the knee group (5.93 vs. 5.21).

"Stiffness" also differed significant between knee and hip patients (5.48 vs. 4.96; p=0.08).

Table 4. Descriptive statistics and score distributions for the different assessments

Assessment	range		joint	N	Mean	SD	p
GP score	0-10		Hip	115	3.97	2.36	0.43
			Knee	105	4.23	2.48	
Kellgren-Score	1-4		Hip	115	2.77	0.82	0.13
			Knee	105	2.59	0.89	
AIMS2-SF	0-10	physical	Hip	114	3.61	1.57	0.15
			Knee	101	3.92	1.64	
		affect	Hip	115	4.20	1.32	0.40
			Knee	104	4.34	1.25	
		symptom	Hip	115	3.05	2.70	0.03
			Knee	105	3.88	2.95	
		social	Hip	114	5.04	2.00	0.58
			Knee	104	5.18	1.87	
		role	Hip	63	8.33	2.69	0.12
			Knee	46	7.41	3.41	
WOMAC	0-10	Pain	Hip	114	5.21	1.99	0.01
			Knee	103	5.93	2.07	
		Stiffness	Hip	115	4.96	1.97	0.08
			Knee	105	5.48	2.43	
		Function	Hip	115	5.59	2.30	0.23
			Knee	105	5.98	2.50	
		Overall	Hip	115	5.25	2.08	0.10
			Knee	105	5.75	2.36	

Figure 2 displays the GP score distribution in relation to the Kellgren score separated by hip and knee. As can be seen, the median of GP scores increases with the Kellgren score. Interestingly, in the hip and in the knee group the GP score achieved the widest range when patients were rated with a Kellgren score of two or four.

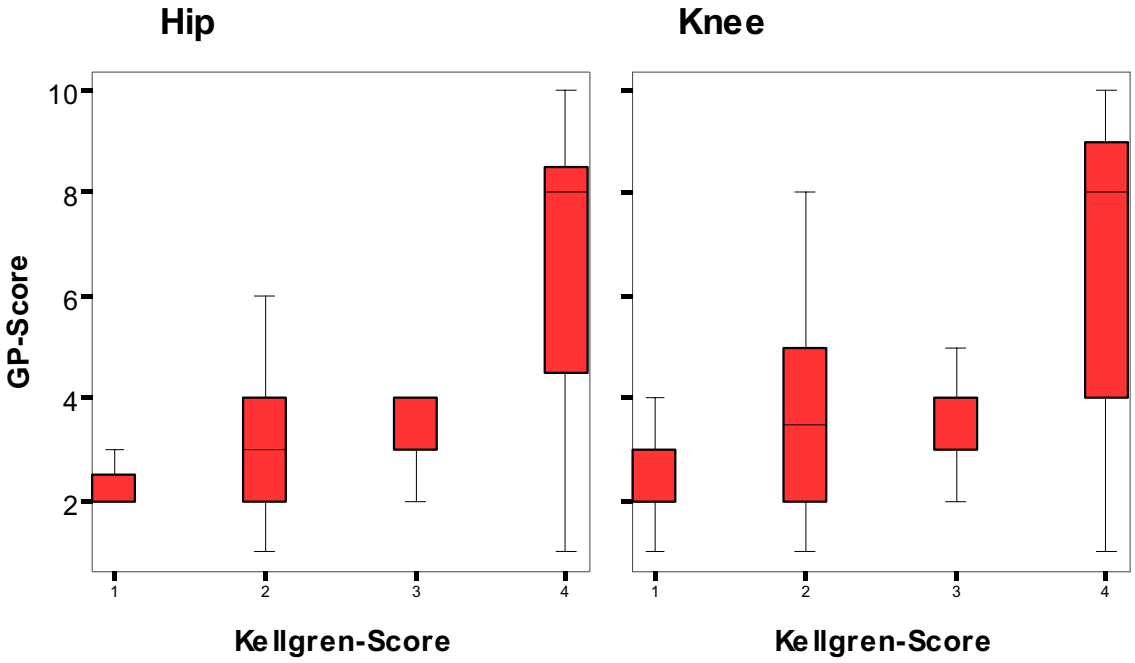


Table 5 displays statistically significant correlations for the GP assessment and the scale "physical" (rho=0.495) and "symptom" (rho=0.598) of the AIMS-questionnaire and good correlations (rho=0.557) with the "pain" dimension of the WOMAC. The radiological grading according to Kellgren and Lawrence correlates quite well with the "symptom" dimension of the AIMS. All other correlations tended to be low, reaching the lowest values for the scales social and role of the AIMS2-SF.

Table 5. Correlations (Spearman rho) of GP score and x-ray findings with AIMS2-SF and WOMAC

	AIMS2-SF					WOMAC		
	Physical	Affect	Symptom	Social	Role (n=109)	Function	Stiffness	Pain
GP-Score	0.495**	0.370**	0.598**	0.161*	-0.165	0.358**	0.373**	0.557**
Kellgren-Score	0.328**	0.320**	0.419**	0.107	-0.214	0.227	0.302	0.303

Level of significance: *p<0.05; **p<0.01

Table 6 displays score distributions in demographic subgroups. Age was positively correlated with the impact of OA on QoL, reflected by higher scores in all instruments in the group aged over 60, despite the "affect" and "social" scale of the AIMS2-SF. Patients with lower educational level achieved higher values in most scores. Women obtained higher values in most scores except for the "role" scale of AIMS2-SF. 111 patients were already retired from work; therefore numbers for the "role" scale were smaller.

Table 6. Mean scores for demographic subgroups

		Sex			Age			Education		
		Male	**Female**	**P**	**< 60**	**>=60**	**P**	**High**	**Low**	**P**
N		123	97		83	137		125	95	
WOMAC	Pain	4.92	6.41	**	4.65	7.11	**	4.62	6.31	**
	Function	6.44	5.26	**	5.13	6.84	**	4.91	6.43	**
	Stiffness	5.59	6.01	**	4.65	6.12	**	4.36	5.86	**
	Global	4.90	6.23	**	8.86	6.52	**	4.65	6.12	**
GPs assessment		3.43	4.94	**	3.36	5.30	**	3.06	4.88	**
x- ray		2.55	2.85		2.58	2.84	**	2.45	2.86	**
AIMS	Physical	3.25	4.43	**	3.20	4.74	**	3,09	4.26	**
	Affect	3.83	4.81	**	3.95	4.79	**	3.90	4.55	**
	Symptom	2.32	4.57	**	2.16	5.22	**	1.83	4.44	**
	Social	4.08	5.02	**	4.05	5.23	**	4.16	8.28	*
	Role	1.74 (n=74)	2.72 (n=35)		2.06 (n=97)	1.98 (n=12)	**	5.25 (n=63)	2.31 (n=46)	

Level of significance: *p<0.05; **p<0.01

Table 7 displays the results of the polytomous ordinal regression analysis that mirrors the dependence of the GP score on age, gender, education, on the AIMS2-SF scales "physical", "affect", "symptoms", "social" and on the WOMAC scales "function", "stiffness", "pain" as well as on the radiological grading according to Kellgren and Lawrence. Interestingly, in contrast to our bivariate comparisons, only "symptoms" and "Kellgren score" emerged as significant influence variables:

$$\hat{\beta}_{SYMPTOMS} = 0.2588,\ 95\%\ CI\ [0.03,\ 0.49],\ p = 0.0267$$

$$\hat{\beta}_{KELLGREN} = 0.6395,\ 95\%\ CI\ [0.29,\ 0.99],\ p = 0.0004$$

whereby $\hat{\beta}_j$ represent the regression coefficient estimations according to the maximum likelihood method[24] for the underlying regression model. Obviously, the impact of "Kellgren score" appears to be stronger and is more significant in comparison to "symptoms".

Conclusion

Physicians' assessment of patients' QoL is mainly influenced by two factors, pain and radiological findings. The results of the present study suggest that other factors, which are known to have an important influence on QoL of patients suffering from osteoarthritis such as socio-economic and psychosocial factors, are not sufficiently considered by the GPs.

Table 7. Results of logistic regression analysis

	Variable	$\hat{\beta}$	P	95% CI
Socio-demographic factors	age	0.0555	0.6611	[-0.19, 0.30]
	sex	-0.0720	0.3530	[-0.22, 0.08]
	education	-0.0693	0.6552	[-0.37, 0.24]
AIMS2-SF	physical	-0.0272	0.8343	[-0.28, 0.23]
	affect	0.0521	0.7276	[-0.24, 0.34]
	symptoms	0.2588	0.0267	[0.03, 0.49]
	social	-0.0107	0.9060	[-0.19, 0.17]
WOMAC	function	0.1235	0.2928	[-0.11, 0.35]
	stiffness	-0.0526	0.6726	[-0.30, 0.19]
	pain	0.1389	0.3545	[-0.16, 0.43]
X-ray	Kellgren-Score	0.6395	0.0004	[0.29, 0.99]

Strength and weaknesses of the study

To our knowledge, this is the first study exploring physicians' assessment of patients' QoL by estimating factors that may influence GPs. Some limitations have to be mentioned. In Germany more X-rays are taken in the care of patients with OA in comparison to other countries[25]. Therefore, influence of X-ray findings on GPs may be higher than in other countries. Assessing the socio-economic status of patients by asking for the annual income is very uncommon in Germany, so the educational level was used instead.

Without a doubt OA has an important impact on patients' QoL. This was revealed by multiple primary care based studies[26,27]. There is also strong evidence that QoL of patients suffering from chronic diseases is influenced by multiple individual factors as for instance support from family, the social situation, affect and mood[7,8,28-32].

Moreover, previous studies indicated that even physical disability cannot only be explained by structural changes in the joint[6,29]. Neither the assessment of correlations nor the logistic regression analysis could identify socioeconomic or psychosocial factors to have important influence on the GPs' assessment. This may indicate that these factors are beyond the scope of physicians, even if the GP, who is more familiar with the patient and his individual situation than all other physicians, is estimating patients' QoL. This is in accordance with findings of previous studies which, for instance, revealed that psychological factors as well as concomitant depressions are often missed by physicians treating OA[10]. In ignoring these factors, GPs could also miss the possibility to involve additional important caregivers or persons out of patients' social context such as a spouse or other family members and friends[33].

Our study suggests that instead of considering these important factors, GPs' assessment of QoL is more focused on evident structural changes as documented in radiographs. Though it has been known for a long time that radiological findings show only poor correlation to pain and patients' QoL, physicians' estimations are still strongly influenced by radiographs. Ignoring psychosocial influence factors may cause a lack of treatment and on the other hand considering factors which are less related to patients' QoL –such as radiological findings– may lead to inadequate treatment. The implications for practice are obvious: our results suggest that physicians should consider physiological and social factors more intensely when treating patients suffering from OA. They should be aware that these factors contribute substantially to patients' QoL and may represent an important target for non-surgical and non-pharmacological interventions. Moreover, GPs should avoid overestimation of X-ray findings and treat patients not pictures.

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Section II

Comorbidity and health service utilisation

Chapter 4

Predictors of depression in a sample of 1,021 primary care patients with osteoarthritis

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Abstract

Objective: Although there is a strong relationship between depression, chronic pain and physical activity, there are few findings regarding the prevalence and predictors of depression in patients with osteoarthritis (OA). The goal of the present study was to assess the prevalence and severity of depression in a large sample of patients with OA and to reveal predictors of depression.

Methods: Patients were approached consecutively in 75 general practices. Of 1,250 distributed questionnaires, 1,021 were returned and analysed. Besides sociodemographic data, medication and comorbidities, depression, and arthritis were assessed using the Patient Health Questionnaire (PHQ-9) and the Arthritis Impact Measurement Scale. A stepwise multiple linear regression analysis with the PHQ-9 score as the dependent variable was performed.

Results: On the PHQ-9, 19.76% of men and 19.16% of women achieved a score of ≥15, indicating at least a moderately severe depression. Significant gender differences could not be revealed. The strongest predictor for depression severity was perceived pain (ß=0.243, $P < 0.001$) and little social contact (ß=0.218, $P < 0.001$). Further predictors were physical limitation of the lower body (ß=0.157, $P < 0.001$) and upper body (ß=0.163, $P < 0.001$), age (ß=0.168, $P < 0.001$), and body mass index (ß=0.080, $P=0.020$).

Conclusion: These findings suggest an increased prevalence of depression among patients with OA and emphasise the need for recognition and appropriate treatment. Most of the revealed predictors are influenceable and should be potential targets in a comprehensive treatment of OA to interrupt the vicious circle of pain, physical limitation and depression.

Introduction

Osteoarthritis (OA) is highly prevalent in the older population and is associated with a substantial impact on patients' quality of life[1]. The most frequent symptoms are chronic pain and physical limitation. Therefore, arthritis represents the most commonly reported physical source of chronic pain in the elderly[2]. Depression is also highly prevalent in the elderly and a common comorbidity of many chronic diseases[3]. The impact on OA, for example, is great because depression has a substantial impact on the two main symptoms of OA: pain and disability. Regarding pain, previous studies have shown that individuals with depression are more likely to report chronic pain and that more than half of patients with chronic pain experience depression[4,5]. In patients with OA, depression was found to be associated with increased pain sensitivity and less effective coping with the illness[6]. Consequently, several attempts have been made to assess the relationship of pain and depression and to explain the psychopathologic process of chronic pain. Dieppe and Lohmander stated that "the association and pathogenesis of pain are in as much need of investigation as joint damage"[7]. A recent meta-analysis pointed out that depression probably is the consequence and not a disposing factor for pain in patients with arthritis[8]. Regarding functional impairment, which represents the second major burden of OA, the causality of the association between physical limitation and depression is also still unclear. Similar as in pain and depression, the relationship seems to be in some way bidirectional[9]. Because it is quite obvious that depression can aggravate the main symptoms of arthritis, many studies have been aimed at revealing risk factors for depression among patients with arthritis. Sociodemographic and psychosocial factors were found to play an important role, but their contribution is not yet clarified[7,10,11]. Moreover, many studies aimed to explain the relationship failed to control for important covariates such as sociodemographic factors, disease duration, comorbidities, level of disability, or social support, which may have an important impact on depression[12–14]. In consequence, the variability of the so far reported data may mainly be due to the measures used and to the controlled factors. Nevertheless, the association between arthritis and depression mediated through pain and functional limitation represents important information for developing clinical and public health interventions, which could interrupt the vicious circle of depression, pain, and functional limitation. Treatment of depression can improve health status and functional ability[15], and screening and appropriate interventions can help prevent subsequent health burdens and related health care costs[16]. Therefore, it is important to identify patients with OA at high risk for depression so

that these patients may be targeted for depression screening and treatment. Knowledge about risk factors or predictors of depression can ease identification of these patients. Consequently, the goal of this study was to assess the prevalence and risk factors of depression in a large sample of patients with OA in a primary care setting.

Patients and methods

The data used for this study were obtained from the baseline assessment of the PraxArt project[17], which aims to improve the quality of life of patients with OA. The project is financed by the German Ministry for Education and Research over a period of 6 years, starting in 2003. A randomly created sample of 75 general practitioners in the areas of Baden-Wuerttemberg and Bavaria was enrolled and recruited the patients. The data for this baseline assessment were collected between March and May 2005 and can be considered a representative reflection of the present situation of patients with OA in primary care in Germany with regard to health status and received care.

Patient inclusion criteria. To be eligible for inclusion, patients had to be at least 18 years of age and diagnosed with OA of the hip or knee according to the criteria of the American College of Rheumatology[18,19]. The patients were asked by the general practitioner (GP) to participate in the study if OA represented the main (or at least one) reason for the current encounter. In each of the participating 75 practices, 15 patients fulfilling the criteria were recruited consecutively so that a total of 1,250 sets of questionnaires were delivered to patients. GPs created a list of all recruited patients. After giving their written informed consent, patients received the questionnaires and a stamped envelope. They were informed that neither the GP nor the practice team had any possibility of finding out their answers. Inclusion of patients did not start until there was a written and unrestricted positive vote of the ethics committee of the University of Heidelberg, which was received in March 2005 (approval number 021/2005).

Data collection. Each patient's set of questionnaires was linked with an identification number to the participant's list, so that data provided by the patients could be checked by comparing them with the patients' files. If differences between patients' answers and the medical file occurred, the data from the file were used. This procedure was performed to assess reliability of answers later in the PraxArt project. Nonrespondents were identified by comparing the GP's list of

recruited patients with received questionnaires. Sociodemographic data (sex, age, ethnicity, educational level, working situation, family situation) were collected. Educational level was defined as follows: ≤1 represented elementary school, 2 represented high school, and ≥3 represented a college degree. Regarding comorbidities, the following comorbid conditions were surveyed: high blood pressure (HBP; >140/90 mm Hg), diabetes, chronic heart failure, coronary vessel disease (CVD), elevated cholesterol level (total cholesterol >200 mg/dl), ulcer or stomach disease, asthma/chronic obstructive pulmonary disease, renal insufficiency, cancer (prior), and stroke (prior).

Depression was measured using the depression module of the German form of the Patient Health Questionnaire (PHQ-9)[20,21]. The PHQ-9 is a completely self-administered questionnaire that enables screening for depression and assessment of depression severity. For each of the 9 depressive symptoms, according to the Diagnostic and Statistical Manual of Mental Disorders, Fourth Edition[22], patients indicated whether, during the previous 2 weeks, the symptoms had bothered them “not at all,” “several days,” “more than half the days,” or “nearly every day,” yielding a score of 0–3. The PHQ-9 severity score thus ranges from 0 to 27. The internal reliability of the PHQ-9 severity measure is excellent with a Cronbach’s alpha between 0.86 and 0.89 [23,24]. Following the recommendation of Kroenke and colleagues[23], we classified patients’ level of depression as mild, moderate, moderately severe, and severe if they scored between 5 and 9, 10 and 14, 15 and 19, and 20 and 27, respectively. Additionally, to compare the rate of depression symptoms with that of other studies, we collapsed the categories into moderate, moderately severe, and severe depression (i.e., PHQ-9 score ≥10) [25,26]. Secondly, we used a stricter cut-off score (PHQ-9 score ≥15), because this score usually signifies the presence of major depression[23].

The impact of OA on patients’ health was assessed by the German Arthritis Impact Measurement Scales Short Form (AIMS2-SF), which provides a comprehensive assessment of patients’ health status including the dimensions: physical limitation, symptom (reflecting perceived pain), social (reflecting social contacts), affect (reflecting mood), and work (reflecting the ability to work). The AIMS2-SF has recently been validated in German using a sample of patients with OA and has proven to be comparable with the original version regarding reliability and validity[27,28]. As suggested in the German validation study, we divided the physical limitation scale of the AIMS2-SF into upper body limitation and lower body limitation.

Statistical analysis. The data were analysed with the SPSS program, version 12.0 (SPSS, Chicago, IL). Because the prevalence of depression differs between men and women in the general population, the results of descriptive statistics were separated by sex[29]. Group comparisons between sexes were made using Students' *t*-test for continuous variables and Fisher's exact test for nominal variables. Analyses of covariance (ANCOVAs), which were adjusted for covariates such as age, disease duration, and number of comorbidities if applicable, were used to compare multiple variables between sexes . Scatter plots were performed, where applicable, to confirm linear relationship. Prior to regression analysis, univariate correlations were calculated. Correlations between sociodemographic or clinical variables and PHQ-9 scores were assessed by computing Spearman's rho or, if linear relationship was confirmed, Pearson's correlation coefficient.

To determine predictors of depression severity, a multiple linear regression analysis was performed with the PHQ-9 score as the dependent variable. Factors were only entered in the regression models if they showed significant correlation ($P < 0.01$) in the univariate correlation analysis. Multicollinearity could be assumed at least for some of the factors, so that a stepwise multivariate regression analysis may have resulted in an artificially high linear regression coefficient R2 due to forced entry in the model of highly correlated factors. Therefore, we used a hierarchical stepwise technique with 2 blocks of variables. The sociodemographic variables were entered in the first block and the disease characteristics were entered in the second block. In a subsequent backward elimination process in every step, the variable with the lowest beta was excluded, if no significance was achieved ($P > 0.01$). This approach has already been chosen by other authors and can be regarded, in a statistical sense, as a conservative approach to assessing predictors[30,31].

Results

Of the 1,311 patients recruited by the GPs, 1,250 agreed to fill out the set of questionnaires; 1,021 sets were returned to the university. At least 11 sets were returned per practice. The main reason given for not participating was time effort. Missing data mainly occurred within the same questionnaires, resulting in 271 questionnaires with missing data. In 123 cases, the data could be completed from the patient's file. The PHQ-9 scores could be calculated in 1,012 cases. A comparison of the 1,021 respondents and the nonrespondents revealed no significant differences regarding sociodemographic variables (age, sex), disease

characteristics (duration of disease), number of comorbidities, and prescribed medication.

Various characteristics of the study sample are displayed in table 1. Of the 1,021 included patients, 347 (34.0%) were men and 674 (66.0%) were women. In comparison with women, significantly more men were married or lived with a partner. The *t*-test for group comparison revealed a significant difference in the (formal) educational level. Differences in body mass index (BMI), age, number of comorbidities and disease duration were not significant between sexes. Regarding ethnicity, >92% of both sexes were white. Regarding pain treatment, the most frequently prescribed medications were nonselective cyclooxygenase inhibitors such as diclofenac. Of both sexes <9% received antidepressants. Regarding comorbidities, more than half of the included patients had HBP, men significantly more frequently than women.

Table 1. Characteristics of the study sample (n=1021)

	Gender				
	Male (n=347/34.0%)		Female (n=674/66.0%)		
	mean	SD	mean	SD	p
Age	65.16	14.75	66.64	15.33	0.166
Duration of OA (years)	14.80	16.18	13.13	11.09	0.098
Body mass index (BMI; kg/m²)	28.39	4.26	28.12	5.16	0.277
No. of comorbidities (0-10)	2.20	1.81	2.24	1.65	0.741
Educational Level (1-3)	2.61	1.11	2.38	0.83	0.001
GP contacts in the last 6 months	4.08	6.29	5.61	8.26	0.002
Radiographs of joint in the last 6 months	0.78	4.15	0.98	4.15	0.121
	Total	%	Total	%	
Married/Living in partnership	278	80.1	376	55.8	0.001
Retired	233	67.1	482	71.5	0.788
Medication					
Acetaminophen	2	0.6	8	1.2	0.056
COX 2-inhibitors	8	2.3	18	2.7	0.236
Nonselective COX- inhibitors	120	34.6	276	41.0	0.059
Opioids	22	6.3	46	6.8	0.429
Other pain relievers	7	2.0	14	2.1	0.514
Antidepressants	31	8.9	48	7.1	0.141
Comorbidities					
High blood pressure	181	52.1	384	56.9	0.001
Elevated cholesterol	124	35.7	245	36.3	0.059
Diabetes	57	16.4	120	17.8	0.068
Chronic heart failure	63	18.1	131	19.4	0.099
Coronary vessel disease	62	17.8	70	10.3	0.009
Ulcer/gastritis	77	22.1	146	21.6	0.341
Asthma/COPD	34	9.8	64	9.5	0.278
Renal insufficiency	23	6.6	33	4.9	0.085
Cancer	21	6.1	16	2.4	0.008
Stroke	16	4.6	30	4.4	0.367

(p-values by means of t-test, Fishers exact test respectively for nominal data)

Among comorbidities that may have an impact on patients' physical activity, cardiovascular diseases were the most frequent: heart insufficiency (18.1% of men and 19.4% of women) and CVD (17.8% of men and 10.3% of women) were much more common than stroke (4.6% men and 4.4% in women).

Regarding the PHQ-9, 344 men (98.9%) and 668 women (99.1%) answered all 9 items. The categories of depression severity according to the PHQ-9 are displayed in table 2 with the categories none (score 1–4), mild (score 5–9), moderate (score 10–14), moderately severe (score 15–19) and severe (score 20–27). As can be seen, 100 men (29.1%) and 233 women (34.9%) were classified as not depressed. With a score of ≥10, 181 women (27.1%) and 107 men (31.1%) were depressed. Using a cut-off score of 15, a total of 196 (19.4%) patients, namely, 68 men (19.8%) and 128 women (19.2%) were classified as depressed.

Table 2. Scores and grading of the severity index of depression (PHQ-9)*

PHQ-9 scoring	Total (n=1012)	Male (n=344)	Female (n=668)	P#
Total score, mean (SD)	15.73 (4.7)	15.33 (4.8)	15.95 (4.6)	
None 1-4	333 (32.9)	100 (29.1)	233 (34.9)	0.11
Mild 5-9	391 (38.6)	137 (39.8)	254 (38.0)	0.06
Moderate 10-14	92 (9.1)	39 (11.3)	53 (7.9)	0.04
Moderately severe 15-19	151 (14.9)	52 (15.1)	99 (14.8)	0.23
Severe 20-27	45 (4.4)	16 (4.7)	29 (4.3)	0.34

* Values are the number (percentage) unless otherwise indicated.

\# Analysis of covariance (adjusted for age, disease duration and number of comorbidities)

Because the prevalence of depression differs in the normal population[15] and in some severe diseases[16], we computed group comparisons for each severity category. Adjusted ANCOVAs (age, disease duration, number of comorbidities) revealed no significant differences ($P > 0.05$) between men and women in the categories moderate, moderately severe and severe. Consequently we abandoned the idea of assessing predictors separately for each sex. A comparison of PHQ-9 scores of patients receiving antidepressants with patients receiving no medication revealed no significant differences, even after adjusting ANCOVAs for age and disease duration for both sexes.

Prior to the regression analysis, bivariate correlations between the PHQ-9 score reflecting the severity of depression, sociodemographic variables and disease characteristics were performed (table 3). Pearson's correlation coefficient was determined if a linear relationship could be confirmed: otherwise, Spearman's rho was calculated. Interestingly, a linear relationship could be confirmed for all of the AIMS2-SF scales, as well as for disease duration, age, number of comorbidities and BMI. Apart from the marital status, all variables showed significant correlations

with the PHQ-9 score, but correlation size was notable only for the AIMS2-SF affect scale (r=0.678, *P* < 0.001); the symptom scale, representing patients' perceived pain (r=0.442, *P* < 0.001); and the lower body limitation scale (r= 0.436, *P* < 0.001).

Table 3. Correlations of patients' demographic and clinical variables to severity index of depression (PHQ-9 score: n=1012)

	Mean	SD	Pearson's r	Spearman's rho	P (two-sided)
Female sex				0.076	0.027
Being married				-0.046	0.191
Education	2.45	0.94		-.0097	0.005
Disease Duration	13.69	13.04	0.097		0.006
Lower body*	2.78	1.98	0.436		<0.001
Upper body*	1.49	2.26	0.326		<0.001
Symptom*	4.90	2.20	0.442		<0.001
Affect*	2.93	1.36	0.678		<0.001
Social*	4.67	1.83	0.354		<0.001
Work*	2.65	2.45	0.225		0.002
Age	66.17	15.16	-0.147		<0.001
BMI	28.21	4.88	0.133		<0.001
Amount of comorbidities	2.22	1.71	0.154		<0.001

* representing AIMS2-SF scales

All variables that showed a significant correlation were entered into the multiple regression analysis with the severity index of depression (PHQ-9 score) as the dependent variable (table 4): sex, educational level and age were entered in the first block, which contained the sociodemographic variables. Of these, only age (ß=0.168, *P* < 0.001) remained in the final model as a significantly contributing determinant. Interestingly, the algebraic sign for the factor age was negative, indicating that older age predicted lower PHQ-9 scores in our study sample. The second block of the hierarchical regression analysis contained the disease characteristics. Of these, the symptom scale, reflecting patients' perceived pain, remained as the strongest predictor with a beta of 0.243 (*P* < 0.001). Also, having few social contacts resulted in higher scores in the AIMS2-SF social scale, remained a predictor (ß=0.218, *P* < 0.001), as did physical limitation of the lower body (ß=0.157, *P* < 0.001) and of the upper body (ß=0.163, *P* < 0.001). The beta of 0.080 for BMI (*P*=0.020) indicated that this variable was only a weak predictor. The adjusted R_2 of the final model was 0.338, indicating that the revealed predictors leave a notable amount of variation of the dependent variable, the PHQ-9 score, unexplained.

Table 4. Predictors of severity index of depression assessed by a stepwise multiple regression model

Dependent: PHQ-9 score	β	SE	T	p
Included				
Age	-0.168	0.010	-4.935	<0.001
Lower body*	0.157	0.107	3.569	<0.001
Upper body*	0.163	0.083	4.240	<0.001
Symptom*	0.243	0.095	5.820	<0.001
Social*	0.218	0.097	6.150	<0.001
BMI	0.080	0.035	2.324	0.020
(Constant)		1.259	7.578	<0.001
Excluded				
Block 1				
Education	-0.006		-0.189	0.850
Sex	0.012		0.345	0.730
Married/partner	-0.014		-0.418	0.676
Block 2				
Disease duration	-0.034		-1.004	0.316
Sum of comorbidities	0.041		1.167	0.244

R^2= 0.345; Adjusted R^2= 0.338; F=51.815 ; p<0.001
*representing AIMS2-SF scales

Discussion

Pain, few social contacts, and physical limitation were revealed as the most important predictors of a high score on the PHQ-9 depression severity instrument. Also, age and BMI contributed significantly to the prediction of PHQ-9 scores. Furthermore, our findings suggest that the point prevalence of depression symptoms among patients with OA in a primary care setting is increased compared with unselected primary care patients of the same age. Interestingly, gender differences in the prevalence of depression as found in the general population[29] and revealed for instance among patients with diabetes[32], did not occur in our study sample.

Previous findings regarding the prevalence of depression among patients with arthritis mainly focused on patients with rheumatoid arthritis; there was no indication of increased prevalence rates among patients with OA if they were assessed[30,33,34]. Contrary to these findings, our data demonstrated that 29% of patients achieved a PHQ-9 score ≥10 and nearly 20% scored ≥15, indicating major depression. Moreover, the mean scores of the PHQ-9 were quite high, with a mean of >15. In comparison, in a study among 3,000 American primary care patients the mean was 5.0 for all patients, 15.1 for patients with a depressive disorder and 18.6 for patients with major depression[19]. A recent study revealed a point prevalence among primary care patients of 5.6% for major depression and 5.2% for minor depression[35]. Our findings indicate a significant increase in the prevalence rate of depression in patients with OA compared with unselected

primary care samples. Prevalence rates of concomitant depression reported for other chronic diseases differ widely: Wiehe et al. revealed a point prevalence of 12.4% among 1,174 men and women with high blood pressure[36] and Odden et al. reported a rate of 17% in patients with chronic kidney disease[26]. Higher rates were reported for patients with chronic heart failure (28.6%)[37], type 2 diabetes (32.9%)[32] and asthma (45%)[38]. But when comparing such prevalence rates, disease characteristics of included patients as well as the method of assessment of depression (self-reported or by physician interview) should be acknowledged because they contribute substantially to prevalence rates[32].

Regarding predictors of depression, pain represented the strongest predictor in our study. Physical limitation, pain and depression have frequently been found to be closely related to each other and many studies have attempted to reveal the causality[4,39,40]. One hypothesis is that one causes the other. Other hypotheses suggest a shared diathesis that increases the risk for individuals to be more susceptible to both. Newer studies in patients with chronic pain suggest the existence of independent neuronal networks for sensory and affective pain elements. These findings suggest that appropriate treatment of depression might increase patients' mood but may not help reduce the pain felt [39]. Regardless of these findings on a neuronal level, it appears that functional ability, depression and social support have a strong impact on an individuals' capacity for occupational adaptation, which is essential for coping with pain[41]. Therefore, even if the causal linkage between depression and physical limitation remains unclear, our finding, that physical disability is a predictor for depression severity, is in accordance with multiple previous studies and most likely reflects a bidirectional relationship: although functional disability can lead to depression, depression has a detrimental effect on physical mobility[42,43].

The importance of the social background has already been mentioned above and its contribution to depression in the general population has been pointed out by many studies in the past[30,44]. Therefore, not surprisingly, it is also an important predictor among patients with OA, as revealed in this study.

The finding that increased BMI represents a (comparably weak) predictor for higher PHQ-9 scores is new. None of the previous studies have assessed BMI as a contributing factor. Nevertheless, the result seems plausible, since an increased BMI represents a further element in the vicious circle of pain, depression and physical inactivity. It seems that increased BMI does not only increase the risk for OA but also the probability of depression. Regarding the lifetime prevalence of depression, which reaches a peak in the fourth and fifth decades as well as at the

mean age of our study sample, which was beyond that time frame: the finding that increased age is a predictor for lower PHQ-9 scores seems plausible[45,46]. Interestingly, neither the duration of OA nor the sum of comorbid conditions contributed to depression severity. Regarding comorbidities, some previous findings indicate that, for instance, heart diseases are risk factors for depression[42]. Nevertheless, we abandoned the idea of controlling the regression analysis for certain comorbidities because of two reasons. Firstly, the contribution of the assessed comorbidities is still unclear, even if there are some indications for certain diseases, such as heart disease. Secondly, it can be assumed that this contribution is mediated by physical limitation, as pointed out by Dunlop and colleagues[42]. Therefore, we supposed that the contribution of comorbidities is mostly reflected in the physical limitation dimension of the AIMS2-SF.

Some further limitations and weaknesses of our study have to be noted. Firstly, even if there are many studies demonstrating that the PHQ-9 has proven to be a sensitive and specific instrument to reveal depression[23,24], the final diagnosis needs to be confirmed by further exploration. This, however, was not the case in our study and would have been difficult to do because of the sample size. Secondly, as already mentioned, it can be assumed that the quantity as well as the quality of comorbidities influence depression. We were only able to control for the number of comorbidities. Finally, previous studies have demonstrated that a lower social status is associated with increased depression due to increased barriers to health care[47]. We did not ask participants about their income, because this is very uncommon in Germany and because low income does not necessarily represent an important barrier for access to the health care system in Germany.

Despite the mentioned weaknesses, this study is the largest study up to now assessing depression in patients with OA in primary care with data collected in individual practices. Moreover, we controlled for more variables contributing to depression than any previous study.

In conclusion, the impact of depression on patients with OA has been documented in many aspects: despite the impact on quality of life, depression has been revealed as a negative predictor of the outcome of surgical interventions[48] and interventions aimed at physical activity[49]. As in the general population, depression influences consulting behaviour and increases health service utilisation[45,50]. In contrast, previous findings indicate that physicians overestimate structural changes in OA and underestimate the contribution of depression to pain perception, functional ability and quality of life[51,52]. Furthermore, previous studies have demonstrated that improved depression care can improve pain and

functional ability among patients with OA[15]. The impact of OA on a patient's life is multifarious and should be treated appropriately. Our findings present some influenceable targets for a multifaceted treatment of OA, which may help increase patients' quality of life.

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Chapter 5

The impact of concomitant depression on quality of life and health service utilisation in patients with osteoarthritis

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Abstract

To assess the impact of concomitant depression on quality of life (QoL) and health service utilisation of patients with osteoarthritis (OA). Data were collected from 75 primary care practices in Germany. In total 1,250 patients were consecutively approached; 1,021 (81.7%) questionnaires were returned and analysed. Measures included sociodemographic data, the Arthritis Impact Measurement Scale (AIMS2-SF) and the Patient Health Questionnaire (PHQ-9) to assess depression. A PHQ-9 score of 15 or higher, was defined as reflecting depression. Patients with a depressive disorder achieved significantly (all $P < 0.001$) higher scores in all AIMS2-SF dimensions. They had more contact with general practitioners ($P < 0.01$), orthopaedics ($P < 0.01$) and with providers of complementary alternative medicine offered, e.g., by healers. Concomitant depression aggravates the burden of OA significantly. This results in increased health service utilisation. Appropriate treatment of depression would appear not only to increase QoL but also to lower costs by decreasing health service utilisation.

Introduction

Recent research has shown that the point prevalence of depression is increased among patients suffering from osteoarthritis (OA) to the hip or to the knee[1]. It could be proved that early recognition and treatment of concomitant depression increases quality of life (QoL) and reduces the burden of disease[2].

Furthermore, it is known that patients with depressive disorders are high utilisers of health services[3]. Most prior studies defined health service utilisation as, e.g., contact with general practitioners (GPs) or physicians overall and did not differentiate between different providers of medical care or different medical services, such as performed X-rays[4]. No prior study assessed providers of complementary alternative medicine (CAM), even though it is known that the use of CAM is quite common among patients with arthritis[5]. In all health care systems OA is associated with high indirect and direct costs[6,7,] and our hypothesis was that the health service utilisation (HSU) of OA patients with concomitant depression is significantly increased compared to controls of OA patients without a depressive disorder. It can be assumed that depression is not only directly linked to increased HSU but also mediates increased HSU by its substantial impact on all dimensions of QoL. Therefore, the aim of this study was not only to assess the impact of depression on the QoL of OA patients but also its impact on health service utilisation including the use of CAM.

Materials and methods

The data used for this study stem from the PraxArt project, which aims to improve the QoL of patients suffering from OA. The project is financed by the German Ministry for Education and Research over a period of 6 years and comprises data on patients with OA from 75 general practitioners in the areas of Baden-Wuerttemberg and Bavaria.

Patient inclusion criteria

The study protocol was approved by the ethics committee of the University of Heidelberg previous to the start of the study in January 2005. Patients were not included unless there was a written and unrestricted positive vote from the ethics committee. To be eligible for inclusion, patients had to be adult and diagnosed with arthritis to the hip or knee according to the ACR criteria.[8,9] All patients who visited their GP because of complaints related to OA were addressed consecutively in GPs' practices. After giving their written informed consent they received the questionnaire and a stamped envelope with the postal address of the university.

The patients were asked to return this questionnaire to the university. They were informed that it was impossible neither for the GP nor the practice team to get knowledge of their answers.

Data collection

Each questionnaire was linked to the list of participants by an identification number; so data given by patients could be checked by comparing them with the patient's file. Sociodemographic data (sex, age, educational level, working situation, family situation) were collected. Regarding comorbidities, the following conditions were collected: high blood pressure, diabetes, heart insufficiency, coronary heart disease, elevated cholesterol level (LDL > 200 mg/dl), ulcer or stomach disease, asthma/COPD, kidney disease, cancer and stroke. If differences between patients' answers and the medical file occurred, the file data were used. In addition to the comorbidities, we asked the patients "Did you have any complaints or notice side effects you assume to be related to the prescriptions you are taking for your arthritis?" Depressive disorders were diagnosed using the depression module of the German Patient Health Questionnaire (PHQ-9).[10] The PHQ-9 is a self-administered questionnaire that enables the diagnosis of major depression and minor depression according to DSM-IV.[11] Moreover, the summarised scales score allows the assessment of the severity of depression. The PHQ-9 has proven to be a valid instrument for such assessments.[12,13] In accordance with recommendations by Kroenke et al. a cut-off of 15 points was used to define depression.

The impact of OA on patients' QoL was assessed by the GERMAN-AIMS2-SF, which represents a reliable, valid and comprehensive tool. It provides a comprehensive assessment of QoL while comprising the dimensions physical limitation, symptom (reflecting perceived pain), social (reflecting social contacts), affect (reflecting mood) and work (reflecting the ability to work). It has recently been validated in the German language in a sample of OA patients.[14] As suggested in this study, we differentiated between upper body limitation and lower body limitation on the physical limitation scale of the AIMS2-SF.

To assess physical activity we used the short form of the International Physical Activity Questionnaire (IPAQ)[15], developed by an international panel of experts (EUPASS) and validated across Europe. Physical activity-related energy expenditures (MET-min/week) were calculated using existing recommendations available at http://www.ipaq.ik.se. For vigorous physical activity, the total of minutes of activity per week were multiplied by the factor 8, for moderate physical

activity by the factor 4, and for walking by the factor 3.3. The sum of these three products is the MET-min/week.

Statistical analysis

The data were transferred into the SPSS program (version 12.0). All data were reported descriptively. Comparisons were made between genders by means of the Student's *t* test or by ANOVAs, which were adjusted for covariates such as age or disease duration if applicable. Group comparisons between depressed and nondepressed OA patients were made by means of ANCOVA [adjusted for age, disease duration, body mass index (BMI)], using a cut-of of 15 on the PHQ-9 score. A Bonferroni post hoc correction was performed to avoid bias of multiple testing where applicable.

Results

Characteristics of the study sample are displayed in table 1. Of the 1,021 included patients, 347 (34.0%) were male and 674 (66.0%) were female; 278 (80.1%) of men and 376 (55.8%) of women were married or lived with a partner. Since most patients had already retired from work (67.1% of men and 71.5% of women), the work scale of the AIMS2-SF was excluded from further analysis. Interestingly, differences in BMI, age, the number of comorbidities and disease duration achieved no significance between genders.

Table 1. Characteristics of the study sample (n=1021)

	Gender			
	Male (347/34.0%)		Female (674/66.0%)	
	mean	SD	mean	SD
Age	65.16	14.75	66.64	15.33
Disease duration (years)	14.80	16.18	13.13	11.09
Body mass index (BMI)	28.39	4.26	28.12	5.16
No. of comorbid conditions (0-10)	2.20	1.81	2.24	1.65
Educational Level (1-3) **	2.61	1.11	2.38	0.83
Married/Living in partnership	278	80.1 (%)	376	55.8(%)

**t-test: p<0.01

Regarding the answer rates within questionnaires, 344 men (99.1%) and 668 (99.1%) women completely answered all nine items of the PHQ-9. As can be seen in table 2, of these, 65 (18.9%) men achieved a score of 15 or higher. In women, 131 (19.6%) reached or surpassed the score level, which is considered to indicate depression. The overall prevalence of depressive disorders according to the PHQ-9 score and including both genders was 19.4%. Gender comparisons by means of

ANOVA (ANCOVA), adjusted for age and disease duration revealed no significant differences in PHQ-9 scores between the sexes.

Table 2. PHQ-9 scores (severity index of depression)

				Fulfilling criteria for		Overall
Gender	**N**	**Mean**	**SD**	**Major Depression**	**Minor Depression**	**Depressive Disorder**
male	344	15.33	4.76	38 (11.0%)	27 (7.8 %)	65 (18.9%)
female	668	15.95	4.63	84 (12.6 %)	47 (7.1 %)	131 (19.,6%)
Total				122 (12.0%)	74 (7.3%)	196 (19.4%)

Table 3 shows a comparison of patients with and without PHQ-9 scores indicating depression. The first section of the table displays the sociodemographic characteristics of the study sample. Group comparisons of these characteristics were performed by means of a *t* test or Chi-square test.

Table 3. Comparison of patients with and without PHQ-9 scores indicating depression

PHQ-9 score	**<15 (n=724)**		**>= 15 (n=288)**		
	Mean	**SD**	**Mean**	**SD**	**p**
Sociodemographics, disease characteristics and comorbidities [a]					
Age	68.12	11.16	65.60	12.46	0.031
Education level	2.48	0.946	2.31	0.882	0.035
Physical activity (IPAQ) (MET-min/week)	2,545.3	1,872.5	2,001.1	1,871.3	<0.001
Disease characteristics					
Duration of OA	13.18	12.991	16.20	13.050	0.007
BMI	27.59	4.21	28.56	5.07	<0.001
Number of comorbidities[c]	2.17	1.81	2.23	1.67	0.781
Number of prescriptions[c]	2.70	4.83	2.92	4.89	0.213
Quality of life (AIMS2-SF dimensions) [b]					
Lower body	2.52	1.85	4.03	2.08	<0.001
Upper body	1.26	2.07	2.68	2.81	<0.001
Symptom	4.61	2.14	6.30	1.96	<0.001
Affect	2.69	1.25	4.10	1.24	<0.001
Social	4.49	1.80	5.54	1.73	<0.001
Perceived side effects	1.87	4.268	4.09	6.617	<0.001
Health service utilisation [b]					
Accupuncture	1.14	4.35	.57	1.76	0.111
GP	4.67	7.35	7.10	8.87	<0.001
Orthopeadics	1.59	3.10	2.90	5.23	<0.001
Healer	0.11	0.97	1.15	6.16	<0.001
Physiotherapy	6.59	12.29	7.30	9.96	0.496
X-ray of joint	0.71	4.03	0.98	4.11	0.041

[a] By means of t test/Chi-square test
[b] By means of ANCOVA, adjusted for age and disease duration
[c] Exclusive depression

As can be seen, patients achieving a higher PHQ-9 score were significantly younger and less educated. Regarding OA, patients with a higher PHQ-9 score suffered from OA longer and had a higher BMI. Neither the differences regarding

comorbidities (exclusive depression and OA) nor the number of prescriptions for these comorbidities were significant. As a consequence of these findings, we adjusted ANOVAs for comparisons of QoL as well as health service utilisation for age, disease duration, educational level and BMI. Even after adjusting these factors, differences remained significant ($P < 0.001$ for all) for all dimensions of QoL, physical activity, contact with GPs, orthopaedics and healers. Differences regarding physiotherapy and acupuncture were not significant. A higher score was also associated with a positive answer to the question on more complaints about self-experienced side effects of OA treatment ($P < 0.001$).

Discussion

Our findings suggest that a concomitant depression in patients with OA has a substantial impact on their QoL. This effect remained even if data were controlled for important covariates that influence OA such as age, disease duration, educational level and BMI. Furthermore, these patients tend towards increased utilisation of the health care system, including visits to GPs and orthopaedics but also regarding the performance of X-rays.

The fact that patients receiving a higher score on the PHQ-9 were younger is in accordance with life-prevalence of depression[16]. Prior research also shown that depression rates among patients with chronic diseases are often increased[17–21] and that depression frequently aggravates the burden of the chronic disease.[22,23] For instance, in rheumatoid arthritis, depression was found to be an independent risk factor for increased mortality[24]. This study group recently showed that depression rates seem to be increased in OA patients as well [1]. Our findings confirmed that like most other chronic diseases, concomitant depression increases the disease burden of OA significantly. In our study sample, patients with a PHQ-9 score equal to or above 15 were also found to be significantly less physically active than patients with a lower score. Our data cannot explain the causal linkage but reflect the bidirectional relationship between physical activity and depression.[20] However, this finding is of importance since moderate physical activity can decelerate the progress of OA and is an important target in the non-surgical treatment of OA.[25] Since depression has been found to be a predictor for the success of interventions aiming at increasing physical activity[26], our results emphasise the importance of the appropriate treatment of depression to increase the success of interventions aiming at increasing physical activity, including Arthritis Self Management Programs.[27]

Prior research has shown that patients with depression tend towards an intensive use of the health service, including physician contacts as well as testing.[3,4] Regarding OA, prior research has found depression to be an important predictor of the outcome of surgical interventions[28]. Hopman-Rock and colleagues found the chronicity of pain to be the most important predictor for health service utilisation. The level of disability and radiological grading was of less importance for visits to GPs as well as specialists. Since depression is known to increase pain in OA patients[2] our findings suggest that depression can work as a catalyser and increase HSU. Brandt et al.[29,] for instance, stated that in patients without radiological damage knee pain might be a manifestation of depression rather than of a joint disease. However, the economic burden of concomitant depression in OA mediated by increased HSU might be underestimated. Interestingly, HSU was focused on GPs, specialists and healers. Treatments such as physiotherapy, which require patients' active participation were not used significantly and more often by patients with a high PHQ-9 score.

Strengths and weaknesses

Several limitations of the study should be mentioned. The assessment was cross-sectional which includes some limitations regarding the association of factors per se. We could only assess associations between e.g. depression and QoL, and, of course, no causal conclusions could be drawn. Furthermore, some of the data regarding HSU were self-reported and could not be confirmed by data from patients' files. The PHQ-9 is a self-administered questionnaire as well, but it has proven to be a sensitive and specific instrument to reveal depression in various studies.[30] To our knowledge, the present study represents the largest assessment ever of the impact of depression on QoL and HSU.

Conclusion

The results emphasise the importance of the awareness of the impact of depression on QoL of patients with OA. Prior research has shown that the appropriate treatment of concomitant depression can reduce the burden of the disease[2] and our data suggest that it would also reduce HSU and costs. Tools such as the PHQ-9, for instance, represent a valid, easy to use and non-time-consuming instrument to assess depression. As prior research has shown, aggressive treatment can increase QoL of OA patients significantly. Our study suggests that this would not only decrease the burden of the disease but would also be a promising approach to decrease the high direct and indirect costs of OA.

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Chapter 6

Association between obesity, quality of life, physical activity and health service utilisation in primary care patients with osteoarthritis

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Abstract

Objective: To assess the association of obesity with quality of life, health service utilisation and physical activity in a large sample of primary care patients with osteoarthritis (OA).

Methods: Data were retrieved from the PraxArt project, representing a cohort of 1,021 primary care patients with OA. In 978 patients, height and weight were measured and the body mass index (BMI) was calculated. The AIMS2-SF was used to assess quality of life (QoL). Data about health service utilisation (HSU) were retrieved by means of patients' medical files. Concomitant depression was assessed by means of the Patient Health Questionnaire (PHQ-9). Patients were grouped into normal weight, overweight and obese according to the definition of the WHO and compared by means of analysis of covariance (ANCOVA).

Results: Obese and overweight persons achieved significantly higher scores on the AIMS2-SF lower body scale, the symptom, the affect and the work scale, indicating an increased burden by OA. The PHQ-9 score increased significantly over the three weight-groups, indicating a positive association of BMI and depression. With increasing BMI, the number of comorbidities increased and physical activity decreased significantly. After controlling for covariates, contacts with orthopaedics and performed X-rays remained significantly higher in obese patients but not contacts with general practitioners.

Conclusion: The results display a strong association of QoL and BMI, resulting in increased use of the health care system. Thus, the study emphasises the need for appropriate approaches in primary care to break the vicious circle of overweight, depression, decreasing physical activity and decreasing QoL.

Background

The relationship between osteoarthritis (OA) and body weight has been recognised for a long time.[1,2] Body weight is the strongest influenceable predictor of OA. During walking, the body weight is transferred three to six times across the knee joint, showing the great influence body weight has for the risk of developing OA, especially in the knee. The Chingford study, for instance, showed that for every two units increase in body mass index, the odds ratio for developing radiographic knee OA increases by the factor 1.36.[3] The Framingham study revealed a risk reduction of 50% for women to develop symptomatic OA if the body weight is reduced by about 5 kilograms.[4] Furthermore, prior findings emphasise that not only the incidence of OA can be influenced, but also the progress of symptomatic OA can be reduced if body weight is reduced.[5] Many prior studies focused on the association between obesity and OA in an epidemiological sense. If quality of life (QoL) was assessed, the studies focused on obese people in the general population.[6] Patterns of OA due to obesity were also approached[7], but interestingly less is known about the specific impact of obesity on OA patients regarding quality of life, especially in large samples of unselected primary care patients.

This research deficit is astonishing especially with regard to economic aspects: direct and indirect costs of OA represent a tremendous burden on the health care systems.[8] Prior research indicated that these costs could be reduced significantly by weight loss: Coggon et al. estimated that nearly a quarter of surgical interventions might be avoided if obese people reduced their body weight by at least 5 kg or to a normal BMI.[9]

Against this background, we assessed the hypotheses that the prevalence of obesity is increased among OA patients and that the disease specific QoL of obese OA patients is significantly reduced compared to OA patients with a normal BMI. Furthermore, we hypothesised that obese patients show an increased use of the health care system compared to control patients with OA and a normal BMI.

Patients and methods

The data are extracted from the baseline assessment of the PraxArt project, which is financed by the German Ministry for Education and Research over a period of six years and which aims to improve the quality of life of patients suffering from OA. Data were collected in a large cross-sectional survey including 75 representative general practitioners (GPs) in the areas of Baden-Wuerttemberg and Bavaria, Germany. These GPs created a representative cohort of OA patients

to enable a long-time follow-up and the possibility to assess different aspects of QoL and received health care. Some of these analyses have been published elsewhere.[10-12]

Patient inclusion criteria

To be eligible for inclusion, patients had to be adult and diagnosed with arthritis in the hip or knee according to the criteria of the American college of Rheumatology (ACR).[13,14] In each of the 75 practices, all patients who visited their GP because of complaints related to OA were addressed consecutively until a maximum of 15 patients per practice was reached. After giving their written informed consent, patients received the questionnaire and a return envelope with the postal address of the university. All patients were informed that neither the GP nor the practice team had any possibility to get knowledge of their answers.

Data collection

Within the project, GPs were asked to note down all patients who would be eligible on a list regardless of whether they agreed to participate or not. This was done in order to enable the comparison between responders and non-responders regarding sociodemographic characteristics later on. Each patient questionnaire was linked to the list with an identification number, so data assessed from patients could be checked by comparing them with the patients' medical files. Sociodemographic data (gender, age, educational level, working situation, family situation) and the following comorbid conditions were retrieved by means of questionnaire: high blood pressure, diabetes, heart insufficiency, coronary vessel disease, elevated cholesterol level (defined as total cholesterol > 200 mg/dl), ulcer or stomach disease, asthma/COPD, renal insufficiency, cancer and stroke. Radiological severity of OA was graded according to the Kellgren and Lawrence score.[15] The educational level was defined adapted to the German school system and according to the years of education: ≤ 7 years: 1; 8-10 years: 2; more then 10 years: 3. Where applicable, patients' answers were checked by comparing them with the patients' files. If differences occurred, the data from the medical files were used. This procedure was performed to assess accuracy of patients' self-reported data later on in the project. The same procedure was performed regarding information about health service utilisation, except for the information of complementary and alternative medicine; since these treatments normally do not require a prescription or are not a consequence of a referral, they are not recorded in the medical file. Depressive disorders were diagnosed using the depression

module of the German form of the Patient Health Questionnaire (PHQ-9).[16] The PHQ-9 is a self-administered questionnaire that permits the diagnosis of major and minor depression according to DSM-IV.[17] with a cut-off of 15 points to define depression according to the recommendations of Kroenke et al.[18] Moreover, the summarised scale score allows assessing the severity of depression. The PHQ-9 has proven to be a valid instrument for those assessments.[19,20]

The impact of OA on patients' quality of life was assessed by the GERMAN-AIMS2-SF, which represents a reliable, valid and comprehensive tool. It provides a comprehensive assessment of QoL while comprising the dimensions physical limitation (divided into upper and lower limb), symptom (reflecting perceived pain), social (reflecting social contacts), affect (reflecting mood) and work (reflecting the ability to work). It has recently been validated in German in a sample of OA patients.[21] As suggested in this study, we separated the physical limitation scale of the AIMS2-SF in upper body limitation and lower body limitation to increase responsiveness.

To assess physical activity (PA), we used the short form of the International Physical Activity Questionnaire (IPAQ).[22] The IPAQ was developed by an international panel of experts (EUPASS), validated in nine European countries, including Germany, and has frequently been used to assess PA in different European countries.[23] One measure of the volume of activity can be computed by weighting each type of activity with its energy requirements defined in Metabolic Equivalents (METs) to yield a score in MET-minutes, whereby METs are defined as multiples of the resting metabolic rate and a MET-minute is computed by multiplying the MET score of an activity by the minutes it is performed for. MET-minute scores are equivalent to kilocalories for a 60 kilogram person. For vigorous physical activity, the total minutes per week were multiplied by factor 8, for moderate PA by factor 4, and for walking by factor 3.3. The sum of these three products is the MET-min/week. Inactivity is defined as a score below 150 min/week. Individuals are sufficiently active if they perform (1) a minimum of three days of vigorous activity of at least 20 minutes per day, or (2) a minimum of five days with PA of moderate intensity or walking of a least 30 minutes per day, or (3) a minimum of five days of any combination of walking, moderate or vigorous PA accumulating to a total of at least 600 MET-min/week. Individuals are highly active if they perform vigorous PA on a minimum of three days accumulating to at least 1,500 MET-min/week, or seven days of any combination of walking, moderate or vigorous PA accumulating to a total of at least 1,500 MET-min/week. Individuals who neither meet the criteria for inactivity nor sufficient or high activity are

insufficiently active. The PA-status (insufficiently active, sufficiently active, and highly active) was defined according to the IPAQ scoring protocol available at http://www.ipaq.ik.se. The categories are adjusted to recommendations of the centres for disease control (CDC) recommendations.[23]
Data were analysed with the SPSS program (version 14.0). The BMI was calculated on the basis of height and weight, measured after the consultation with the GP. The definitions of the certain groups “normal”, “overweight” and “obese” were based on the definition of the World Health Organization (WHO). The study protocol was approved by the ethics committee of the University of Heidelberg previous to the start of the study in January 2005. Inclusion of patients did not start unless there was a written and unrestricted positive vote of the ethics committee. This vote was received in March 2005 (approval number 021/2005).

Statistical analysis
All data are reported descriptively. Group comparisons between the three BMI groups regarding QoL, health service utilisation and physical activity were made by means of analysis of covariance (ANCOVAs). Adjustments were made for covariates such as age, disease duration, the radiological grading according to Kellgren and Lawrence and number of comorbidities where applicable. Dichotomous variables, as for instance comorbidities, were compared by means of Chi-square-test.

Results
Of the 1,250 questionnaires distributed, 1,021 (81.7%) were returned. In 978 cases, body weight and height were measured by the GPs. 347 (34.0%) of the 1,021 included patients were male and 674 (66.0%) were female. The comparison of patients who returned their questionnaire with the non-responders did not reveal significant differences regarding the following characteristics which could be retrieved form the medical file: sex, age, duration of OA and number of comorbidities as well as number of prescriptions. 278 (80.1%) men and 296 (43.9%) women were married or lived with a partner. 233 (67.1%) men and 482 (71.5%) women had completely retired from work. Most of the missing data referred to sociodemographic variables and could be completed by means of the patients’ medical files. Details about the study sample, separated by BMI, are shown in table 1. The displayed p-values are the result of group comparisons between the normal weight and the overweight group and between the overweight and the obese group. As can be seen, the groups did not differ regarding age and

duration of disease. Both the radiological grading according to Kellgren and the number of comorbidities increased significantly with an increasing BMI. The educational level decreased from normal weighted patients to obese patients.

Table 1. Baseline characteristics of study sample

	BMI							
	≤24.9		p*	25-29.9		p*	≥30	
	n	%		n	%		n	%
Total (978)	251	25.7		402	41.1		325	33.1
female	180	71.7		255	63.4		208	64.0
	Mean	SD		Mean	SD		Mean	SD
Age (in years)	66.9	13.33	0.295	68.09	11.12	0.062	66.36	11.23
Educational level	2.62	1.03	0.039	2.44	0.91	0.033	2.34	0.86
Duration of OA (in years)	13.41	15.18	0.651	13.95	13.27	0.558	13.40	10.79
Amount of comorbidities	1.69	1.283	<0.001	2.19	1.73	<0.001	2.72	1.86
Kellgren score*	2.26	0.68	0.044	2.53	0.92	0.038	2.76	0.77

* by means of ANCOVA, Chi-Square test respectively for comparison normal vs. overweight and overweight vs. obese

Table 2 provides information about the association of patients' comorbidities and the BMI. As can be seen, the prevalence of high blood pressure was significantly higher in the overweight group (compared to normal weight; $p<0.001$) and also significantly higher in the obese group than in the overweight group ($p=0.002$).

Table 2. Association of comorbidities with obesity (n)

	BMI					total
	≤24.9	p*	25-29.9	p*	≥30	978 (%)
High blood pressure	95	<0.001	229	0.002	223	547 (55.9%)
Heart insufficiency	37	0.143	78	0.709	67	182 (18.6%)
Coronary vessel disease	15	<0.001	62	0.838	52	129 (13.2%)
Diabetes	15	<0.001	62	<0.001	93	170 (17.4%)
Cholesterol > 200	86	0.087	143	0.092	131	360 (36.8%)
COPD / Asthma	13	0.212	32	0.005	50	95 (9.7%)
Renal insufficiency	8	0.139	24	0.421	24	56 (5.7%)
(history of) Ulcer (stomach)	59	0.129	75	0.129	76	210 (21.5%)
(prior) Stroke/TIA/PRIND	6	0.083	23	0.076	12	41 (4.2%)
(history of) cancer	8	0.137	13	0.089	14	36 (3.5%)

* ANCOVA, adjusted for age for comparing normal vs. overweight and overweight vs. obese

Similar findings could be revealed for the prevalence of diabetes. Regarding coronary vessel disease, only differences between the normal weighted patients and the other groups achieved significance but not when we compared overweight and obese patients. 21 men and 16 women reported about a history of cancer or current cancer disease, significant differences between the groups did not occur.

Regarding OA specific QoL (table 3), differences between overweight and normal-weight patients were not significant in any dimension, including the PHQ-9 score which was used to assess depression. Significant differences occurred in the lower body scale, the symptom scale, the affect scale and the PHQ-9 score when the BMI surpassed 29.9 m/kg² in comparison to the overweight as well as to the normal-weight group. The upper body scale did not differ between the three groups, a finding which is most likely due to the study sample that consisted only of patients with OA to the knee or hip. Also, there were no significant differences between all groups regarding scores of the social scale, which reflects social networks and support, and the work scale. However, it has to be acknowledged that the work scale was only applicable in 263 cases, since most of the patients were already retired.

Table 3. Impact of BMI on OA related quality of life

	BMI							
	≤24.9		P*	25-29.9		p*	≥30	
	Mean	SD		SD	Mean		Mean	SD
AIMS2-SF scales								
Lower body	2.46	1.97	0.409	2.59	2.014	<0.001	3.31	1.89
Upper body	1.47	2.35	0.637	1.56	2.43	0.553	1.46	2.02
Symptom	4.55	2.25	0.158	4.80	2.15	0.029	5.31	2.17
Affect	2.66	1.31	0.073	2.85	1.27	<0.001	3.22	1.42
Social	4.49	1.83	0.173	4.68	1.80	0.173	4.87	1.86
PHQ-9 sum score	14.32	4.59	0.165	14.85	4.44	0.002	16.67	4.93

* by means of ANCOVA, adjusted for age, disease duration, Kellgren and Lawrence-score and number of comorbidities for comparing normal vs. overweight and overweight vs. obese

Table 4 displays the comparison of PA between the three weight groups by means of ANCOVA (adjusted for age, disease duration and comorbidities). As can be seen, PA decreased significantly from patients with normal weight to overweight and to obese patients.

Table 4. Physical activity according to IPAQ scoring, separated by BMI

	≤24.9			25-29.9			≥30	
N	251 (25.7%)		p*	402 (41.1 %)		p*	325 (33.1%)	
IPAQ-scoring	Mean	SD		Mean	SD		Mean	SD
Vigorous activity (min/week)	121.3	(169.1)	0.001	101.2	(155.9)	0.007	70.1	(113.4)
Moderate (min/week)	137.8	(158.2)	0.004	112.8	(147.2)	0.001	94.2	(117.9)
Walking	275.8	(284.8)	0.002	249.9	(271.8)	0.009	242.5	(238.2)
Sitting	2139.2	(879.5)	0.003	2088.1	(855.5)	0.004	2031.9	(977.9)
Total	2674.1	(1959.5)	0.002	2552.0	(1921.5)	0.005	2438.7	(1799.2)
Activity group (%)								
Insufficiently active	126	40.1	0.003	202	50.2	0.008	228	70.1
Sufficiently active	109	43.4	0.067	176	43,8	0.079	89	27.4
Highly active	16	6.3	0.042	24	5.9	0.039	9	2.8

* by means of ANCOVA, adjusted for age, disease duration, Kellgren and Lawrence-score and number of comorbidities for comparing normal vs. overweight and overweight vs. obese

The health service utilisation (HSU) patterns of the study sample are displayed in table 5. In unadjusted analysis, visits to GPs increased significantly with the BMI. Since visits to GPs may often be related to other reasons than OA, we adjusted the ANCOVA for comorbidities (as displayed in table 5). Interestingly, the significant difference between normal-weight and overweight patients faded. However, the difference between obese and normal-weight patients remained significant (p=0.002) even after adjusting for the number of comorbidities. Visits to orthopaedics as well as performed X-rays remained associated significantly with the BMI after adjustment.

Table 5. Health service utilization according to BMI

	≤24.9		p*	25-29.9		p*	≥30	
	Mean	SD		Mean	SD		Mean	SD
Contacts with GPs	5.56	9.73	0.059	4.46	5.73	0.051	5.43	7.81
Contacts with Orthopaedics	1.51	2.78	0.049	1.70	2.95	0.001	2.26	4.72
Use of complementary and alternative medicine	0.69	4.99	0.567	0.23	1.47	0.098	0.06	0.66
Use of Physiotherapy	5.36	8.82	0.478	6.97	12.75	0.081	7.78	13.06
Performed X-rays	0.62	3.02	0.003	0.83	3.67	0.002	1.01	4.10

* by means of ANCOVA, adjusted for age, disease duration, Kellgren and Lawrence-score and number of comorbidities for comparing normal vs. overweight and overweight vs. obese

Discussion

The findings of our study suggest an increased prevalence of overweight and obesity among primary care patients with OA. Furthermore, the burden of OA increased with the BMI and thus confirmed our hypothesis that QoL of OA patients is inversely correlated with the BMI. QoL of patients with OA is mainly determined by pain and physical disability. As our results show, pain as well as physical disability increased with patients' weight. In respect to QoL, patients with OA can be compared to primary care patients in general: as Sach et al. assessed health related quality of life (HRQL) with three different instruments, the EQ-5D, the EQ-VAS and the SF-6D and also found obesity to be associated with lower HRQL.[24]
Bramlage et al. found a prevalence of 37.9% of overweight persons and 19.4% of obese persons among all primary care attendees in Germany.[25] Rates of overweight/obesity increased steadily with the number of comorbid conditions and were highest in patients with diabetes (43.6/36.7%) and hypertension (46.1/31.3%), followed by patients with cardiovascular disorders. With 41.1% overweight and 33.1% obese patients, the prevalence rates we found in patients with OA are significantly higher. Similar results in a cross-sectional study were found by Wannamethee et al. who showed that the prevalence of CV risk factors

and morbidity, disability and medication use increased significantly with increasing overweight.

Obese patients were more likely to be referred to a specialist and received significantly more X-rays than non-obese OA patients. Regarding encounters with GPs, the initially significant difference disappeared after adjusting for the number of comorbidities. It can be discussed if this adjustment is appropriate since many of the comorbidities were associated with obesity. However, the focus of this study was OA-related HSU. Nevertheless, the revealed HSU patterns are in line with other findings showing that increase in body weight is associated with increase in medical care costs compared to weight maintenance.[26]

The positive effects of PA on the QoL and well-being, but also on the course as well as on the symptoms of OA, has been shown in multiple studies.[27] Especially for patients with OA in the knee, strengthening the musculus quadriceps femoris can reduce pain and slow down the progress of OA most probably mediated by increased stability to the joint.[28,29] Even though a causality cannot be assessed due to the cross-sectional design of the study, our results, showing that obese OA patients have a significantly reduced level of physical activity, emphasise the need for lifestyle counselling.[30]

Obese patients in our study were significantly more limited in functional disability than non-obese patients. This finding may be due to two different reasons: first of all, the findings regarding perceived pain suggest that these patients simply suffer from more pain that limits functional ability. Secondly, muscle strength, especially the musculus quadriceps femoris has been shown to be of great importance for the stability of the knee and the incidence, progress and symptoms of OA. As Zoico et al. could show, a high BMI and high body fat were associated with greater probability of functional limitation.[31] The skeletal muscle index (SMI) was the strongest predictor for functional disability of patients (without OA).

Prior research has shown that the prevalence of depression and depressive mood among OA patients is increased compared to the normal population of the same age.[20] Physical limitation (especially to the lower body), pain and social contacts were revealed as most important predictors for a clinically relevant depressive disorder (minor or major depression). Interestingly, being overweight was not associated with a higher PHQ-9 score (compared to normal weight), but obesity was. This is an important finding since prior research showed that there is some kind of bidirectional relationship between functional disability and depression: although functional disability can lead to depression, depression has a detrimental effect on physical mobility.[32]

The association between obesity and depression has been assessed in a number of studies, including longitudinal studies. Results suggest that obesity predicts later depression.[33] Our data, showing that obese patients have significantly higher PHQ-9 scores, are in line with these findings.

Some weaknesses of our study have to be acknowledged: our data are not able to assess causality of the association between QoL, physical activity and the BMI. But they confirm the relationship in a large sample of primary care patients and emphasise the influence of obesity on QoL, PA and HSU. Despite the study's weaknesses, to our knowledge, it is the largest study assessing the association of BMI, QoL and HSU in primary care patients with OA so far.

Conclusion

It has been known for a long time that obesity is the strongest modifiable risk factor for OA and recent research has also shown that the association with the waist circumference is similar.[34]

Prior research has shown that GPs' management of overweight and obesity is largely deficient, predominantly due to four interrelated factors: (1) doctors' poor recognition of patients' weight status, (2) doctors' inefficient efforts at intervention, (3) patients' poor acceptance of such interventions and (4) dissatisfaction with existing lifestyle modification strategies. Counselling patients to change their lifestyle is a huge challenge, but it has to be the first approach to OA, according to all guidelines. Recent studies suggested that more intense approaches such as telephone monitoring can increase the effect of PA counselling in primary care.[10,35] Evidence-based concepts such as the "5A-approach", which originally has been developed for smoking cessation, need to be implemented in the counselling strategy for OA.[36] Our study underlines the need to break the vicious circle of increase in body weight, decrease of physical activity, increase in OA related pain and depression. More research is needed to provide evidence-based lifestyle counselling programs for physicians, especially the GP, who in most cases, is the main care provider for patients with OA.

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Chapter 7

Pain and osteoarthritis in primary care: factors associated with pain perception in a sample of 1,021 patients

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Abstract

Objective: Pain represents one of the most important predictors of quality of life in patients with osteoarthritis (OA). Prior studies were conducted in hospital settings and /or failed to control such important factors as depression, obesity or physical activity. Therefore, the aim of the study was to determine factors associated with pain intensity in a large sample of OA patients in primary care.

Design: A cross-sectional survey with a questionnaire containing sociodemographic data, the short form of the Arthritis Impact Measurement Scale (AIMS2-SF), and the Patient Health questionnaire (PHQ-9) to assess concomitant depression. A hierarchical stepwise multiple regression analysis with the AIMS2-SF dimension "symptom" reflecting patients' pain intensity as the dependent variable was performed.

Patients: 1,021 patients from 75 primary care practices.

Results: In the regression model 4 factors remained explaining 47.9 % of the variation in the dependent variable ($p<0.0001$): severity of depression, reflected in the PHQ-9 score, influences pain intensity the most (beta = 0.459, $p<0.001$). Functional disability of the lower limb accounted for a beta of 0.427 ($p=0.003$). A low educational level was associated with increased pain scores (beta=-0.321; $p=0.029$) as was disease duration (beta=0.178; $p=0.017$). Social contacts/networks, addressed by the AIMS social scale, accounted for a beta of 0.211 ($p=0.040$).

Conclusion: A variety of physical and psychological factors was associated with pain intensity. Appropriate pain treatment of OA patients in primary care should consider as many of these factors as possible. Further research is needed to assess if a more comprehensive and proactive approach will result in less pain and in increased quality of life.

Introduction

Osteoarthritis (OA) is highly prevalent in the general population and its prevalence is expected to increase further in the upcoming years. Increasing life expectancy and obesity as well as decreasing physical activity are the main reasons for this trend.[1] OA not only leads to disability, it is also often associated with pain and decreased quality of life.[2] The majority of OA patients is treated in primary care, but recent research indicated that this care needs to be improved.[3]

Assessment of OA patients' pain intensity in daily practice is associated with several problems. Firstly, the correlation between radiographic changes and reported pain is weak.[4,5] Obviously, the degrees of pain and disability vary widely in subjects with the same degree of pathomorphological damage to the joint, and thus radiological damages are a poor predictor for patients' pain. Secondly, prior studies revealed multiple factors that are associated with pain intensity: some of them found sociodemographic factors such as age, gender and marital status to be important variables.[6,7] Others emphasised disease characteristics such as the duration of the disease, the body mass index (BMI) and accompanying comorbidities as important factors.[8,9] Moreover, patients with OA seem – as many chronically ill – to be prone to depression and depressed mood.[10] Therefore, some studies focused on the complex relation between chronic disease, depression or depressed mood and perceived pain in OA.[11-14]

In addition to these internal characteristics, external factors such as an intact social network, which provides social support, contribute substantially to the coping with pain.[15] This has already been assessed in intervention studies showing that involvement of the spouse in arthritis self-management programs increases the success of such programs.[16]

Obviously, many factors influence the perception of pain in arthritis[17,18] and interestingly, more studies focused on patients with rheumatoid arthritis than on patients with OA, even though the prevalence of OA is much higher. If OA patients were assessed, sample sizes were small and important factors which could influence pain, such as obesity, physical activity, disease duration and radiological severity were not controlled.[9,19-22] As a consequence of the current research, Dieppe et al. recently stated in *The Lancet*: "The associations and pathogenesis of pain are in as much need of investigation as joint damage".[18] And Craemer et al. suggested that studies aiming to explore pain among OA patients should define how pain is identified, differentiate community and hospital subjects and control for other factors potentially associated with pain: obesity, comorbidity, muscle weakness and physical fitness.[11] Consequently, the aim of this study was to

assess a wide range of factors which could be associated with pain intensity in a large sample of OA patients in primary care and to reveal their contribution to pain intensity. The prevalence of knee and hip OA differs between genders, and women frequently achieve higher scores on instruments assessing pain.[20,23] Therefore, we hypothesised that factors associated with pain intensity differ according to gender.

Methods

The data used for this study are retrieved from the baseline assessment of the PraxArt project [ISRCTN87252339]. The project is financed by the German Ministry for Education and Research over a period of six years starting in 2003 (grant number 01GK0301) and comprises data from a representative sample of 75 general practitioners' (GPs) practices in the areas of Baden-Wuerttemberg and Bavaria. The aim is to learn about patients' needs, provided care and to develop tailored multifaceted interventions in order to increase quality of life.[24]

Patient inclusion criteria

To be eligible for inclusion patients had to be 18 or older and diagnosed with arthritis to the hip or the knee according to the ACR criteria.[25] In every practice, 15 patients were contacted in consecutive order of appearance in the practice, and if the reason for the current encounter was related to OA, they were informed about the option to participate in the study.

Data collection

After giving their written informed consent, patients received a package of questionnaires which they were asked to return to the university either by returning it using an enclosed stamped envelope or by putting it in a sealed box at their GPs practice. Neither the GP nor the practice team had the possibility to get knowledge of the patients' answers. Patients received written reminders from the university, but were also reminded by their GP to return the questionnaires.

Each questionnaire was linked to the participants list with an identification number, so data provided by the patients could be checked by comparing them with their medical files. If differences occurred, the data from the medical file were used for further analysis. This procedure was applied to assess reliability of patients' answers later on in the project. Since GPs were also asked to record patients who denied participation, it was possible to compare the non-responders to the

participants with regard to most sociodemographic variables, comorbidities and medication.

Demographics

Sociodemographic data regarding sex, age, educational level (defined as follows: 1 ≤ elementary school; 2=high school; 3 ≥ college degree), working situation (1=unemployed or retired, 2=part-time job, 3= full-time job), partnership (1= living alone, 2= married/living with partner) were collected.

Comorbidities

Based on prevalence and clinical relevance in the observed age group, the following ten comorbid conditions were controlled: high blood pressure (HBP:RR>140/90 mmHg), diabetes, heart insufficiency (HI), coronary heart disease (CHD), elevated cholesterol level (defined as total Cholesterol > 200 mg/dl), ulcer or stomach disease, asthma/chronic obstructive pulmonary disease (COPD), renal insufficiency, cancer and stroke.

Depressive disorders

Since depressive disorders were found to be associated with pain intensity[26], we assessed severity of depression by means of the depression module of the German form of the Patient Health Questionnaire (PHQ-9).[27] The PHQ-9 is a self-administered questionnaire used to diagnose major depression and minor depression according to DSM-IV and to assess severity of depression.[28,29] The PHQ-9 has proven to be a valid instrument for those assessments.[30,31]

Quality of Life

The most widespread instrument to assess QoL among OA patients is the AIMS, available also in a revised short form, the AIMS2-SF.[32-34] It represents a reliable, valid and comprehensive tool and has recently been validated in German in a sample of OA patients.[33,35] It covers the five dimensions physical limitation (divided in upper limb and lower limb), affect, social, work and symptom. The symptom scale addresses pain intensity in 4 items and has frequently been used to assess pain in intervention trials, including surgical interventions.[20,36] The social scale is defined as reflecting patients' social interactions and network. It contains 4 items asking about the frequency of personal contacts with friends and relatives (including phone contacts) but also if relatives and friends are sensitive to the individuals' needs. The affect scale reflects patients' mood without assessing

depression as an outstanding disease. The work scale is applicable only to patients who are not retired since it assesses restrictions in daily work caused by OA. Scale internal validity and reliability for all scales is excellent.[35]

Physical activity

Prior studies have shown that the strength of Musculus quadriceps femoris contributes to the course of the disease as well as to the perceived pain.[37] Due to the large sample size it was not possible to assess individuals' muscle strength, but as suggested by Creamer et al., we decided to examine physical activity by means of the International Physical Activity Questionnaire (IPAQ). The IPAQ was developed by an international panel of experts (EUPASS) and validated in nine European countries, including Germany. It has frequently been used to assess physical activity in different countries.[38,39] The purpose of the International Physical Activity Questionnaire (IPAQ) is to provide a set of well-developed instruments that can be used internationally to obtain comparable estimates of physical activity. It was considered to be the most advanced international approach to assess type of activity, frequency, duration and intensity of physical activity at a population level. The physical activity (PA) status (insufficiently active, sufficiently active and highly active) was calculated according to the recently revised scoring protocol following the recommendations of the IPAQ Executive Committee for the 7-days short-version, available at www.ipaq.ki.se. The PA categories are adjusted to recommendations of the CDC recommendations.[40]

Radiographic severity

Severity of radiographic changes were classified according to Kellgren et al.[41]

Data Analysis

The data were transferred into the SPSS program (version 12.0). First of all, descriptive analyses were undertaken for all variables, separated by gender. Continuous variables were reported using mean, standard deviation (SD) and t-tests for group comparisons. For dichotomous variables, absolute numbers and percentages were displayed, and gender comparisons were made using the Mann-Whitney U test. Differences between genders regarding dimensions of quality of life (assessed by means of AIMS2-SF) were assessed by means of ANOVAs (ANCOVAs) adjusted for BMI, disease duration, age, number of comorbidities and depression (PHQ-9 score) and a post hoc Bonferroni correction was performed to avoid bias of multiple testing. Prior to the regression analysis a

correlation analysis, by means of calculating Pearson's r was performed. The dependent variable of the regression was the symptom scale of the AIMS2-SF. Factors entered into the regression model were chosen according to the achieved significance in the correlation analysis ($p \leq 0.05$). To assess predictors, different types of multiple linear regression models are available. We chose a hierarchical stepwise technique with sociodemographic variables entered in the first block and disease characteristics entered in the second block.

Results

Overall, 1,250 questionnaires were distributed to patients of which 1,021 (81.68%) were returned and analysed. As far as data were available in patient files, the non-respondents were compared to the respondents. Regarding important socio-demographic variables (age, gender) as well as the available disease characteristics (duration of disease, no. of comorbidities, health service utilisation and prescription of pain relievers), both groups did not differ significantly. Over 90% of the enrolled patients were Caucasian. If missing data occurred, they mainly occurred within the same questionnaire, in total in 271 of the 1,021 questionnaires. In 123 cases the data could be completed from the patient file. A radiological scoring according to Kellgren was only available in 735 (72%) cases.

Table 1 displays the characteristics of the study sample separated by gender.

Table 1. Characteristics of the study sample separated by gender (n=1021)

	Gender			
	Male (347/34.0%)		Female (674/66.0%)	
	mean	SD/%	mean	SD/%
Age	65.16	14.75	66.64	15.33
Duration of OA (years)	14.80	16.18	13.13	11.09
Body mass index (BMI)	28.39	4.26	28.12	5.16
No. of comorbid conditions (0-10)	2.20	1.81	2.24	1.65
Educational Level (1-3)**	2.61	1.11	2.38	0.83
Married/Living in partnership**	278	80.1 (%)	376	55.8(%)
retired	233	67.1(%)	482	71.5(%)
Radiographic severity (Kellgren score)*	2.76	0.92	2.53	0.77
IPAQ score (MET/week)	2356.2	(1982.5)	2108.3	(1879.6)
Quality of life (AIMS2-SF dimensions) [#]:				
Lower body **	2.39	1.71	2.98	2.08
Upper body	1.38	2.33	1.54	2.22
Symptom **	4.49	2.17	5.12	2.18
Affect **	2.60	1.28	3.10	1.36
Work * (126 women / 89 men)	3.08	2.67	2.34	2.23
Comorbidities	Total	%	Total	%
High blood pressure**	181	52.1	384	56.9
Elevated cholesterol	124	35.7	245	36.3
Diabetes	57	16.4	120	17.8
Heart Insufficiency	63	18.1	131	19.4
CVD	62	17.8	70	10.3
Ulcer/Gastritis	77	22.1	146	21.6
Asthma/COPD	34	9.8	64	9.5
Renal Insufficiency	23	6.6	33	4.9
Cancer	21	6.1	16	2.4
Stroke	16	4.6	30	4.4

p <0.05; ** p < 0.01 in group comparison (t-test, Mann-Withney U test, respectively); [#] by means of ANCOVA adjusted adjusted for BMI; disease duration, age, number of comorbidities and (PHQ-9 score)

As can be seen, 347 (34.0%) of the 1,021 included patients were male and 674 (66.0%) were female. 233 (67.1%) men and 482 (71.5%) women had retired from work. Significantly more men than women were married or lived with a partner. A significant difference in the (formal) educational level was revealed in group comparison. BMI, age, number of comorbidities and disease duration did not differ significantly between genders. Regarding comorbidities, more than half of the included patients suffered from HBP, men significantly more frequently than women. Cardiovascular diseases were the most frequent comorbidity: heart insufficiency (18.1% of men and 19.4% of women) and CVD (17.8% of men and 10.3% of women) were much more common than stroke (4.6% men vs. 4.4% in women).

Table 2 displays the bivariate correlation analyses with the symptom scale. Significant correlations (p<0.01) occurred in the sociodemographic variables gender, education and marital status, but Pearson's r for all correlations was quite

low (-0.111-0.210) indicating only weak correlations. Since most of the patients had already retired from work, the work scale of the AIMS2-SF was also excluded from further analyses. Notable high values for Pearsons' r were revealed in the lower body scale, the upper body scale and the PHQ-9 sum score as well as in the affect scale.

Table 2. Correlations of patients' demographic and clinical variables with the symptom scale of AIMS2-SF

		Symptom scale Pearson r	Significance
Gender**		0.210	0.021
Age		0.012	0.372
Educational level**		-0.142	0.009
Marital status*		-0.111	0.045
Disease duration**		0.189	0.004
BMI**		0.182	0.009
Kellgren score*		0.388	0.007
IPAQ score (MET/week)*		0.125	0.044
No. of comorbidities**		0.202	0.009
PHQ-9 sum score**		0.439	0.010
AIMS2-SF scales	Lower body	0.551	0.009
	Upper body	0.437	0.008
	Affect	0.471	0.002
	Social	0.119	0.007
	Work	0.322	0.009

level of significance: *p<0.05; **p<0.01;

The BMI showed only a weak correlation, as did disease duration. Nearly all variables showed significant correlations, but the size of the correlation was notable only for the AIMS2-SF affect-scale (r=0.678; p<0.001), the symptom scale representing pain intensity (r=0.442; p<0.001) and the lower body limitation scale (r=4.36; p<0.001).

Except age, which achieved no statistical significance in the bivariate correlation analysis, and the Kellgren score, which was not available for all patients, all factors mentioned in table 2 were entered in the final regression model. Table 3 displays the results of the hierarchical stepwise regression with the symptom scale of the AIMS2-SF as the dependent variable. The adjusted R^2 of 0.465 indicates that the remaining factors are able to explain nearly half of the variance in the dependent variable. Four factors finally remained: the affect scale of the AIMS2-SF, assessing patients' mood, was the strongest predictor for pain with a beta of 0.459 (p<0.001), followed by the lower body scale of the AIMS, reflecting the physical limitation to the lower limb (beta=0.427; p=0.003). A higher educational level was associated with less pain intensity, as the negative algebraic sign indicates (beta=-0.321; p=0.034). A better social network (resulting in lower scores of the social scale) also predicted less perception of pain (beta=0.211; p=0.042). Interestingly, the

PHQ-9 score did not remain in the final model. It was excluded in the last step of the model (beta=0.129; p=0.223) after the variable “disease duration” (beta=0.118; p=0.111). The adjusted R^2 of 0.465 indicates that the remaining factors are able to explain nearly half of the variance in the dependent variable.

Table 3. Predictors of pain assessed by stepwise multiple regression model

Dependent: symptom Unadjusted R^2 = 0.479 Adjusted R^2= 0.465 F= 18.233; p<0.0001	B	SE	Change in R^2	p
Affect*	0.459	0.114	0.147	<0.001
Lower body*	0.427	0.108	0.137	0.003
Educational level	-0.321	0.141	0.062	0.034
Social*	0.211	0.1.07	0.081	0.042

* AIMS2-SF scale

Discussion

Depressed mood, physical limitation to the lower limb, educational level, and social contacts are the most important factors associated with pain perception of patients suffering from osteoarthritis to the knee or hip.

With respect to these factors, the finding that depression is associated with increased pain intensity in patients suffering from musculoskeletal disorders has been known for a long time.[9,42,43] Tsai et al., for instance, performed a path analysis aiming to explain depression in OA patients: pain, disability and social support remained in the final model. Contrary to their initial hypothesised model and similar to our findings, gender and age did not remain in the final model. The revealed association between physical limitation and pain is most likely bidirectional, so our results emphasise again the strong impact of physical limitation on perceived pain.[44,45] The patients in our sample suffered mainly from OA to the hip or knee. Therefore, we used the GERMAN-AIMS2-SF with a separated assessment of upper and lower limb, as suggested in the validation study previously conducted by this study group.[35]

The fact that the educational level remained as a predictor in the regression model is in accordance with our assumptions, and confirms previous findings emphasising the importance of education for coping strategies and managing daily live in chronic diseases.[14] Furthermore, a low educational level has been found to be associated with both radiographic as well as symptomatic knee OA.[46] However, it has to be considered that many factors such as different working situations or access to health care can mediate the association between education and perceived pain.[11] The social scale of the AIMS2-SF addresses patients’ social

contacts and social support. Since several studies have pointed to the importance of the social network for coping with chronic diseases and especially with pain, our results confirm prior findings in a large sample of primary care patients.[12,15,47] So, interventions aiming at social support by simple monthly telephone calls[48] or spouse assistance have shown to improve patients' QoL.

As already mentioned, none of the previous studies assessed such a large variety of factors that might be involved in pain in OA patients, such as e.g. the BMI, physical activity, depression, localisation of OA. Furthermore, if assessing OA patients, they enrolled only a small number of patients.[11] Due to this, comparisons between our results and previous studies are only possible to a limited extent. For instance, Thumboo and colleagues conducted a comparable survey among 126 Chinese patients.[7] Additional to Chinese ethnicity, work and education, age and disease duration were predictors for pain intensity: a result we could not confirm. However, they defined disease duration as the time period since the first physical limitation occurred whereas we defined it starting from when OA was first diagnosed. In addition, it can be assumed that the social network of most Chinese people as well as the accessibility to health care differs completely from the situation in Germany. Nevertheless, our results are not conflictive to previous findings: age, sex, marital and socioeconomic status, duration of disease, BMI, amount of chronic diseases, social support and psychosocial factors have been revealed as important influences on pain in prior studies.

Some weaknesses of the study have to be noted. Firstly, we failed to control for individuals' catastrophising, which has been found to be of great importance for the coping with pain. [49] Although it is known that catastrophising is also associated with factors we controlled, as, e.g., depression and mood, this limits our findings. Secondly, the radiological severity was not available for all patients. Nevertheless, the strength of this study is that a wide variety of factors which have been shown to be associated with pain singularly or in combination has been assessed within one study. Furthermore, results from hospital-based examinations cannot easily be transferred to the general population. With over 1,000 patients from 75 solo practices this study enrolled about five times more patients than prior studies assessing pain in OA patients.

Pain is an important target in the treatment of OA.[50] It has not only substantial impact on patients' QoL, it is also associated with further complications such as the risk of falls among women.[51,52] Currently, pain treatment – especially in primary care – focuses on pharmacological treatment, but NSAIDs and opioids are associated with multiple problems, especially in older patients with various

morbidities.[53] Therefore, inadequate pain treatment cannot only cause avoidable impact of OA on patients QoL, it can also be a source of high secondary costs.[54] A variety of physical and psychosocial factors was associated with pain intensity in the present sample. It is indispensable to aim at all targets in order to relieve patients' perceived pain, to reduce the risk of side effects of pharmacological treatments and to increase QoL. We think that current care for OA patients should include awareness for psychosocial stress and depression. Current research shows that pain treatment in primary care often misses these targets and needs to be improved.[3] The event-driven, reactive approach in pain treatment applied nowadays should be replaced by a more proactive approach acknowledging these factors. Our results should encourage assessing the effect of more complex approaches in randomised trials.

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Section III

Improving the quality of care

Chapter 8

Satisfaction of osteoarthritis patients with provided care is not related to the disease specific quality of life

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Abstract

Background: Osteoarthritis (OA) has a high prevalence in primary care. Patient satisfaction is an important indicator for the quality of care provided to OA patients. Little is known about satisfaction of patients with this condition in a primary care setting in Germany. The aim of the study was to assess current satisfaction of patients and reveal possible disease and quality of life related predictors.

Methods/Design: 75 German GPs approached 1,250 patients with OA consecutively. Sociodemographics, OA-specific quality of life (GERMAN-AIMS2-SF), comorbidities and depression (using PHQ-9) were assessed. Patient satisfaction was measured by means of the EUROPEP instrument. A stepwise linear regression analysis with the EUROPEP score as dependent variable controlled for the amount of GP visits was performed to assess predictors of satisfaction.

Results: 1,021 OA patients returned the questionnaire. The adjusted R^2 of the final model was 0.270 ($p<0.001$). Beside the duration of OA, no disease related factor was associated with patient satisfaction: Main predictors were the PHQ-9 score (beta=-0.372; $p<0.001$), age (beta=-0.185; $p<0.001$), living alone (beta=-0.209; $p<0.001$), number of comorbidities (beta=-0.152; $p<0.001$), duration of OA (beta=-0.105; $p=0.008$).

Discussion: The finding that depression and social factors are more important for patient satisfaction with provided care than disease related aspects suggests that these factors need to be considered carefully in treatment. This represents a big challenge within an increasingly specialised healthcare system. The general practitioner as the regular and first-choice provider of health care seems to be the most appropriate instance who can accomplish that.

Background

In recent years, sensitivity to the patients' perspective on the provided care has increased. Physicians as well as policy makers have recognised that meeting the patients' needs and priorities is an important indicator for the quality of care provided to patients. Since they also contain important information to improve the quality of care, several instruments have been developed to assess patients' perspectives on provided care, mostly conceptualised as patient satisfaction. But health care systems across Europe vary widely in terms of practice organisation, role of the GP and accessibility of the health care system; in Germany, for example, most practices are single practices. To allow comparisons across the systems, it is important to have an instrument that can be used in different settings. The EUROPEP has been developed by the EQuiP task force on Patient Evaluations of General Practice Care to satisfy these needs.[1] It is currently the most widespread instrument to assess patient satisfaction with care in general practice. So far, researchers focused mainly on assessing patient satisfaction and comparing data of different countries.[1,2] Other studies aimed to reveal factors associated with the practice, e.g. practice size, number of GPs, or GPs' working hours, which have shown to influence patient satisfaction.[3,4] Regarding specific chronic diseases, only a few studies have assessed patient satisfaction and if, they focused on process parameters: Nau et al., for instance, found more frequent HbA1c monitoring as well as foot exams and counseling to be associated with higher satisfaction in diabetes patients.[5]

Osteoarthritis is a chronic condition with a high and still increasing prevalence in western countries and frequently associated with pain and disability.[6,7] Consequently, the WHO has declared the current decade as "bone and joint decade".[8] The main care provider for OA patients is the GP. The aim of our study was to assess the extent of patient satisfaction with care provided by their GP and to reveal predictors of satisfaction in patients with OA. We hypothesised that patient satisfaction is associated with OA-specific quality of life.

Methods

Study design

The data reported in this study were retrieved from the PraxArt project, a project conducted in primary care in Germany. This project aims to improve the quality of care which results in improved quality of life of primary care patients suffering from OA. Therefore, a large cohort of primary care patients with OA was created and frequent follow-ups as well as intervention trials are performed within this cohort.[9]

The presented data are retrieved from the baseline assessment. Initially, about 500 GPs in the areas of Baden-Wuerttemberg and Bavaria, who fulfilled the inclusion criteria, were invited by a formal letter of the Department of General Practice and Health Services Research of the University Heidelberg to participate in the study. A representative sample of 75 GPs was finally included. All GPs had a contract with all of Germany's health insurancers, which assured that patients of all social levels had unlimited admission to the practice.

Patient inclusion criteria

To be eligible for inclusion patients had to be adult and diagnosed with arthritis to the hip or to the knee according to the ACR criteria.[10,11] Patients were addressed by the participating GPs in consecutive order of appearance in the practice and informed about the option to participate in the project. After giving their written informed consent, they received the questionnaire and a return envelope with the postal address of the university to ensure that neither the GP nor the practice team had any possibility to get knowledge of the patients' answers. Reminders were sent out twice, and additionally the GPs reminded the patients to return the questionnaires without knowing who had already returned it.

Instruments

To assess patient satisfaction with the GP and the medical practice, we used the internationally standardised and validated EUROPEP (European Task Force on Patient Evaluations of General Practice) questionnaire.[1,12] After being tested in an international validation study, the EUROPEP became the most widespread instrument to assess patient satisfaction.[1] The questionnaire contains 23 items relating to specific aspects of family practice during the past 12 months allowing patients themselves to evaluate the quality of care they have received. The patients respond to each item on a five point Likert scale (1 = "poor", 5 = "excellent"). The questionnaire covers two dimensions of care: a general practitioner evaluation (communication, technical aspects and information giving; items 1-17) and a general practice evaluation (items 18-23).[1] The EUROPEP usually achieves high response rates, so that missing values are rare. In the cross European validation study, the internal consistency achieved a value of 0.96 for items 1-16 and 0.87 for items 17-23. As in the other studies, we calculated the percentage of patients rating the item under consideration as "excellent" or "good". Since we focused on satisfaction with the GP, the correlations as well as the regression analysis were performed with the sum score of the items 1-17.

Other measures

A large number of further data were addressed within the PraxArt project.[9] GPs created a list of all addressed patients which was linked with the medical file. Due to this list, an analysis of non-respondents regarding sociodemographics (sex, age, educational level ranging from 1 (no school degree) to 5 (university degree), working situation, family situation as well as duration of OA, comorbidities, prescriptions and health service utilisation was possible. In addition to the EUROPEP instrument, the patient questionnaires comprised a number of other instruments including the GERMAN-AIMS2-SF[13] and the PHQ-9. The AIMS2-SF is one of the most widespread instruments to assess the OA-specific quality of life.[13] The PHQ-9 was used to address severity of depression; it is a sensitive and specific instrument to assess severity of depression, especially for screening purposes in a primary care setting.[14,15]

Patients were asked about comorbidities (high blood pressure, diabetes, heart insufficiency, coronary heart disease, elevated cholesterol level, ulcer or stomach disease, asthma/chronic obstructive pulmonary disease (COPD), kidney disease, cancer and stroke) as well as about health service utilisation (GP contacts, contacts with orthopaedics, use of complementary and alternative medicine and all OA-related treatments as injections, physiotherapy, etc. To assess accuracy and reliability of patients' answers later on in the project, patients' answers were checked by comparing them with the medical file as far as possible. If differences occurred, the data of the medical file were used.

Data analysis

Patients' information on medication and health care utilisation were checked by three research assistants, visiting each medical practice. The study protocol was approved by the ethics committee of the University Hospital Heidelberg.

Statistical analysis

The data were transferred into the SPSS program (version 14.0). Mean and standard deviation are provided for the scores of the 23 items of the EUROPEP. Spearmans' rho was calculated in order to assess correlation of the EUROPEP sum-score of items 1-17 (satisfaction with GPs) with sociodemographics, disease characteristics and disease-specific quality of life. A stepwise linear regression analysis was performed. The predefined significance for inclusion in the next step was 0.05. R^2 and adjusted R^2, displaying the amount to which the remaining

factors explain variation in the dependent variable were provided as well as the F-statistic and p-values.

Results

In total, 1,311 patients were addressed by their GPs. 1,250 of them agreed to complete the questionnaire. Of those, at least 11 patients of each medical practice responded, leading to 1,021 (81.7%) returned questionnaires. Regarding available data, including sociodemographic variables, comorbidities and medication, no statistically significant differences could be revealed between the non-respondents and the respondents. The main reason given for not participating was a lack of time. Among the enrolled patients, 347 (34.0%) were male and 674 (66.0%) were female.

Significantly ($p<0.01$) more men were married or lived with a partner (men: 278; 80.1%; (women:376; 55.8%). Most patients (223; 67.1% of men and 482; 71.5% of women) had already retired. Due to this, the “work” scale of the AIMS2-SF was excluded from further analysis since this scale is only applicable to patients who are still in employment. Table 1 displays the characteristics of the study sample.

Table 1. Baseline characteristics of the study sample

	n	Mean (SD) / %
Age (years)	868	67.39 (11.72)
Duration OA (years)	958	13.69 (13.04)
Female	674	66.0%
Married/Living in partnership	654	64.0%
Retired	705	69.0%
Upper body	1021	1.41 (2.23
Symptom	1021	4.62 (2.42
Affect	1021	2.72 (1.51
Social	1021	4.56 (1.95
BMI	978	28.18 (4.70)
No. of comorbidities	1021	2.22 (1.71)
PHQ sum score	834	15.74 (4.69)
Educational level	1021	2.52 (2.05)
High blood pressure	565	55.3 %
Elevated cholesterol	369	36.1 %
Diabetes	177	17.3 %
CVD	122	11.9 %
Asthma/COPD	98	9.6 %

Table 2 displays the scores of the EUROPEP items in sequential order. As in most other studies the total amount and percentages of patients voting “good” or “very good” on the specific item were displayed. We also report the response rate and the rate of patients who mentioned “not applicable” in the specific item. As can be

seen, the response rate was high, only in three items, about 30%, indicated that the answer was not applicable.

Table 2. Descriptive values of the EUROPEP items

What is your opinion of the GP and/or general practice over the last 12 months with respect to...		Good / excellent response (%)	No answer or not applicable (%)
1	Making you feel you had time during consultation?	77.2	1.9
2	Interest in your personal situation?	76.8	2.2
3	Making it easy for you to tell him or her about your problem?	59.2	3.1
4	Involving you in decisions about your medical care?	69.4	2.8
5	Listening to you?	82.2	0.4
6	Keeping your records and data confidential?	89.5	11.4
7	Quick relief of your symptoms?	38.4	2.1
8	Helping you feel well so that you can perform your normal daily activities?	49.4	4.9
9	Thoroughness?	58.1	2.6
10	Physical examination of you?	86.5	12.1
11	Offering you services for prevention of diseases (e.g. screening, immunisation)?	32.7	9.8
12	Explaining the purpose of tests and treatments?	56.4	4.8
13	Telling you what you wanted to know about your symptoms and / or illness?	33.3	4.5
14	Helping you deal with emotional problems related with your health status?	39.6	8.6
15	Helping you understand the importance of following his or her advice?	42.7	4.3
16	Knowing what they had done or told you during former contacts?	54.8	5.4
17	Preparing you for what to expect from specialist or hospital care?	38.6	31.2
18	The helpfulness of the staff (other than the doctor)?	55.4	3.4
19	Getting an appointment to suit you?	51.8	2.1
20	Getting through to the medical practice on the telephone?	59.4	4.5
21	Being able to speak to the general practitioner on the telephone?	31.6	34.2
22	Time spent waiting in the waiting room?	22.4	3.9
23	Providing quick services for urgent health problems?	55.6	35.2

Table 3 displays the correlations of sociodemographics and disease characteristics with the sum score of the items 1-17 of the EUROPEP addressing satisfaction with the care provided by the GP. Interestingly, gender was not significantly related to the EUROPEP score. Significant correlations were revealed for the marital status, BMI, the amount of comorbidities, the PHQ-9 score as well as the number of received prescriptions. Regarding OA-specific QoL, all AIMS2-SF scales showed significant ($p<0.001$) correlations to the EUROPEP. Since the “affect” scale of the AIMS2-SF, addressing patients’ mood, showed a high correlation to the PHQ-9 sum score, we did not enter this scale in the regression model due to the obvious redundancy.

Table 3. Correlations of the EUROPEP (1-17) sum score and sociodemographic and disease characteristics

	n	Spearman's rho	p*
Living in Partnership	999	-0.082	0.010
Educational level	996	-0.051	0.106
BMI	976	0.243	0.000
Duration of OA	945	-0.199	0.001
Sex (being female)	1021	0.098	0.087
No. of comorbidities	1017	0.162	0.000
PHQ-9 sum score	832	-0.272	0.000
Prescriptions	1017	0.076	0.015
Contacts with orthopaedics	1021	0.024	0.219
Performed X-rays	736	0.038	0.118
AIMS 2-SF dimensions			
Lower body	1021	0.229	0.000
Upper body	1021	0.142	0.000
Symptom	1017	0.203	0.000
Affect	1017	0.303	0.000
Social	1017	0.172	0.000

Table 4 displays the results of the final regression model which was adjusted for age and sex. It explains 27.0% of variation in the EUROPEP 1-17 sum score as dependent. A high score in the PHQ-9, representing more depression symptoms was associated with a lower EUROPEP score (beta=-0.372; p<0.001). Not living in a partnership also predicted lower EUROPEP scores (beta=-0.209; p<0.001) as well as age (beta=-0.185; p<0.001). Interestingly, the number of comorbidities, which was positively correlated to the EUROPEP score turned into a negative predictor of patient satisfaction after adjusting for age and sex (beta=-0.152; p<0.001). Duration of OA was also a weak negative predictor of satisfaction (beta=-0.105; p=0.008). Interestingly, and controversially to our hypothesis, none of the AIMS2-SF dimensions remained as a predictor.

Table 4. Stepwise Regression with the EUROPEP (1-17) sum score as dependent

R^2=0.279; adj. R^2= 0.270, F=29.421; p<0.0001	Beta	T	p
PHQ-9 sum score	-0.372	-80.968	<0.001
Age	-0.185	-40.386	<0.001
Partnership (living alone)	-0.209	-50.361	<0.001
No. of comorbidities	-0.152	-30.740	<0.001
Duration of OA	0.105	-20.666	0.008

Discussion

Our hypothesis that satisfaction of OA patients is related to their disease-specific quality of life was not confirmed since none of the AIMS2-SF dimensions remained in the final regression model. Regarding OA characteristics only the duration of OA

remained as a predictor and was associated with decreased satisfaction. Increased depression symptoms, reflected in higher PHQ-9 scores, increased number of comorbidities and living alone were associated with less satisfaction with the GP as well as a longer duration of OA. To our knowledge this is the first study addressing patient satisfaction regarding a certain disease and aiming to reveal associations with disease characteristics.

Study sample

Representing nearly two-thirds of the included patients, women dominated the study sample. Since patients were consecutively addressed by the GPs, this finding is most likely due to the different prevalence rates of OA in gender: the WHO reports a prevalence of symptomatic OA of 18% in women and 9% in men[16], matching the observed rate of 2:1.

Overall scores

Previous studies using the EUROPEP have revealed high patient satisfaction with the GP in different health care systems across Europe.[17] Overall, the scores in our assessment reflected a positive evaluation of the GPs, especially in items 1 to 7.[2] But the EUROPEP also quite nicely reflects the impact of OA on the evaluation of the GP: some items, as for instance items 7 and 8 addressing relief of symptoms and empowerment of the individuals' capability to handle daily living, were reasonably lower than in previous studies. This finding most likely reflects the clinical characteristics of OA, where pain relief is a major challenge. Similarly, the low values in item 9 "Thoroughness" and item 14 "Dealing with emotional problems" are most likely related to the increased prevalence of depression in OA.[18,19] Furthermore, studies showed that GPs' recommendations regarding the illness as well as its course are often vague.[20] This finding is reflected in the scores of item 11 ("Offering you services for preventing disease?") and item 13 ("Telling you what you wanted to know about your symptoms and/or illness?") which were significantly lower than in other studies assessing patient satisfaction in a more general study population.[21]

Correlation and regression analysis

Since the results of previous studies suggest that women and older patients tend to report higher satisfaction with their GPs, we adjusted our regression analysis for both variables.[2] This revealed an interesting finding: the number of comorbidities, which was positively correlated to the total score turned into a negative predictor in

the regression analysis. We assume that this is related to the association of age and number of comorbidities. This emphasises that non-adjusted results of such surveys need to be interpreted with caution. In the final model, the remaining variables account for an explanation of 27% of the variation in the EUROPEP (1-17) score. First of all, it has to be noticed that our hypothesis that satisfaction may be related to the OA-specific QoL was not confirmed. Furthermore, there was no association between satisfaction and performed procedures as for instance performed X-rays or contacts to orthopaedics. This is in contrast to a prior study which focused on the influence of process parameters and showed increased satisfaction with performed procedures, home visits and parameters related to the medical practice organisation.[5] OA patients obviously do not regard more of these contacts or procedures as increased quality of care.
However, it should be acknowledged that many of these factors interfere with each other since chronification of symptoms as well as pain are related to psychosocial factors and depression.[22,23]

Strengths
The strengths of our survey are obvious: we enrolled a large number of patients that can be regarded as representative of OA patients in primary care. Furthermore, the survey was conducted in a naturalistic primary care setting.

Limitations
Some limitations have to be noted; first of all it is known that the EUROPEP is limited by some ceiling effects which were also revealed in this study. Furthermore, as already mentioned, all doctor's practices were single-handed – as most medical practices in Germany are. This may result in a doctor-patient-relationship that is different from situations where several GPs treat the same patient. This may limit transferability to health care systems other than the German system.

Conclusion
Altogether our study revealed three main findings: patient satisfaction is not dominated by disease-specific QoL, at least not in OA patients. Our results rather suggest that a good doctor-patient-relationship, sensitivity towards concomitant depression and the social background of the patient influences patient satisfaction to a higher degree than the frequency of treatments and contacts with specialists. Most importantly, the needs of older patients, suffering from various chronic

diseases and tending to lower mood or depression, are not appropriately addressed in the current system. Since nowadays the social network as an important source of support for chronically ill patients increasingly disintegrates in most industrialised countries [24-26], a “natural” source to handle this situation is fading away. It could be assumed that the established trend to an increasingly specialised and fragmented health care system will not meet the needs of these patients appropriately.[27] The general practitioner as the regular and first-choice provider of health care seems to be the most appropriate professional to achieve this.

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Chapter 9

The Chronic Care Model: congruency and predictors among primary care patients with osteoarthritis

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Abstract

Objective: The Chronic Care Model (CCM) and the 5A-approach have achieved widespread acceptance and reflect the core elements of patient-centred care in chronic diseases, including osteoarthritis (OA). The aim was to assess to what extent current care for patients with osteoarthritis accords with the CCM in Germany. Furthermore we aimed to reveal possible predictors to assess whether certain patients are more likely to receive care complying with the CCM than others.

Methods: A cross-sectional observational study addressing 1,250 patients from 75 primary care practices in Germany. 1,021 (81.7%) of the administered 1,250 questionnaires were returned. The Patient Assessment of Chronic Illness Care (PACIC-5A) was used to assess accordance to the CCM, and the 5A-approach. Impact of OA was assessed by means of the Arthritis Impact Measurement Scale (AIMS2-SF); the Patient Health Questionnaire (PHQ-9) was used to assess depression symptoms. Two stepwise multiple linear regression models with the PACIC sum score and the 5A score as dependents were performed to reveal predictors of a high accordance to the CCM and to the 5A-approach, respectively.

Results: With a mean of 2.79 in men (SD 0.83) and 2.67 in women (SD 0.89; p for difference=0.89), the PACIC sum score was notably lower than in previous studies conducted in HMO settings in the US. The PACIC score was associated with a higher educational level (beta= 0.421; p=0.008) and younger age (beta=-0.319; p=0.016); the 5A score was predicted by educational level (beta=0.344; p=0.002), age (beta=- 0.386; p=0.004) and the PHQ-9 score (beta=- 0.288; p=0.005).

Conclusions: Younger and better educated patients achieve higher scores on the PACIC score, indicating that their care accords to a higher degree with the CCM. Whether this reflects differences in physicians behaviour toward different patient groups or rather different demands of these patient groups cannot be concluded from the data presented. Further research is needed to confirm our results and assess possible implications for implementing the Chronic Care Model in primary care.

Objective

Chronic diseases like diabetes, hypertension, arthritis and asthma are expected to increase tremendously in the upcoming years.[1] They are associated with high economical costs, but also with a high burden on the individuals' quality of life. Multiple interventional studies have been conducted to increase quality of life of patients with various chronic diseases. Based on the evidence of these interventions Wagner et al. have developed the Chronic Care Model (CCM) as a conceptual framework.[2-4] Current care for the chronically ill is often event-driven despite solid evidence that a structured, planned and proactive approach to chronic diseases helps to reduce the burden of many chronic diseases.[5] The CCM contains 6 key dimensions of care: organisation of health care, clinical information systems, delivery system design, decision support, self-management support and community resources. A recent review of the literature reiterates that successful improvement strategies concerning chronic diseases are consistent with the concept and components of the CCM.[6] The CCM has achieved widespread acceptance, and recently an intense discussion has started among German physicians if and how the CCM or its components can be implemented in health care.[7,8] At the annual meeting of the German Association of Family Medicine (DEGAM) in 2006 a statement has been launched reflecting the intention to implement the CCM or at least some elements thereof in primary care. Nevertheless, no data are available to date showing to what extent current primary care for the chronically ill is congruent to the CCM. To assess the congruency of provided health care to the CCM, Glasgow et al. developed the "Patient Assessment of Chronic Illness care" (PACIC).[9] It is organised according to the key elements of the CCM and assesses the behaviour of professionals and practice teams from a patient's perspective. The PACIC contains 20 items assessing 5 scale constructs: patient activation, delivery system design/decision support, goal setting/tailoring, problem solving/contextual, follow-up/coordination. "Patient activation" assesses to what extent the patient was motivated and supported by the physician to initiate changes, "decision support" assesses if the patient was supported e.g. by booklets and how satisfied he was with the organisation of his care. "Tailoring" assesses to what extent general instructions and suggestions were adapted to his personal situation. "Problem solving" addresses how the physician dealt with problems which interfered with achieving predefined goals. Finally, "follow-up" addresses how frequently and consequently the whole process was followed-up. Recently, a German version of the PACIC 5A has been validated in a sample of osteoarthritis patients.[10] Its psychometric properties have been

reported in detail elsewhere[10]: Cronbach's alpha ranged from 0.78 to 0.90, the test-retest validity, estimated by the intra cluster correlation coefficient (ICC) was at least 0.77.

The "5A" model represents an evidence-based approach to induce a behavioural change.[11] Originally developed for smoking cessation it represents the recommended counselling approach for behavioural changes according to the recommendations of the US Preventive Services Task Force (USPSTF). The key elements are: assessment of present behaviour (Assess), patient counselling (Advise), collaborative agreement with the patient about realistic goals (Agree), assisting the patient during his lifestyle changes (Assist) and frequent follow-ups (Arrange).[12] Glasgow et al. expanded the PACIC by including 6 items assessing to what extent physicians' counselling reflects the 5A-approach. They validated the PACIC-5A in a sample of diabetes patients.[12]

The aim of this study was to assess the congruency between care in general practice in Germany and the CCM as well as between general practitioners' (GPs) counselling style and the 5A-approach. Since we assumed that care and counselling may differ according to sociodemographic, or disease-related characteristics, we aimed to reveal possible predictors of the PACIC-5A score.

Methods

Recruitment of patients and data collection

The PraxArt-project, performed by the University Hospital Heidelberg and financed by the German Ministry for Education and Research (BMBF), intends to improve quality of life of patients suffering from osteoarthritis.[13] 1,021 OA patients from 75 primary care practices in Germany are currently enrolled in this project. The 75 practices are located across the areas of Baden-Württemberg and are a representative sample of German primary care practices: e.g. most of them are single-handed. The anonymous questionnaires are linked within the project via a code-list to the medical file of the practices. Thus, detailed data about sociodemographic variables, duration of OA as well as information about comorbidities, medication, and health services utilisation were available and considered in the analyses. Since GPs prepared a list of all patients addressed these data were available for respondents as well as non-respondents. Inclusion criteria were to be aged over 18, meeting the criteria of OA to the hip or knee according to the American College of Rheumatology (ACR)[14,15] and sufficient German language skills to understand and answer the questionnaire. In all 75 practices GPs consecutively asked patients enrolled in the PraxArt-project to

answer the PACIC-5A. After giving their written informed consent they received the questionnaire and a return envelope to the university. Patients were informed that their GP had no possibility to get knowledge of their answers and were asked to complete the questionnaire on their own. Inclusion of patients did not begin unless there was a written and unrestricted positive vote of the ethics committee of the University of Heidelberg which was received in March 2005.

Depression was measured using the depression module of the German version of the Patient Health Questionnaire (PHQ-9).[16,17] The PHQ-9 is a completely self-administered questionnaire that enables screening for depression and assessment of depression severity. The PHQ-9 score ranges from 0 to 27 with higher scores indicating a poorer health status. The impact of OA on patients' health was assessed by the AIMS2-SF, which provides a comprehensive assessment of patients' health status including the dimensions physical limitation, symptom (reflecting perceived pain), social (reflecting social contacts), affect (reflecting mood), and work (reflecting the ability to work). It has recently been validated in German using a sample of OA patients, and regarding reliability and validity proved to be comparable to the original version (18;19). The AIMS2-SF dimensions score between 0 and 10, with 0 representing the best and 10 representing the worst health status. Based on clinical relevance in primary care, the following comorbid conditions were collected from the medical record: high blood pressure (defined as > 140/90 mm Hg), diabetes, chronic heart failure, coronary vessel disease (CVD), elevated cholesterol level (total cholesterol > 200 mg/dl), ulcer or stomach disease, asthma/chronic obstructive pulmonary disease (COPD), renal insufficiency, (prior) cancer and (prior) stroke. Educational level was assessed on five (nearly equidistant) stages: (1) no school degree, (2) basic degree (<=7 years of education), (3) <=10 years of education, (4) college degree, (5) university degree.

Statistical analysis

Data were transferred into the SPSS program (version 14.0) after questionnaires were scanned. Scores were calculated according to the scoring instructions for the PACIC-5A questionnaire, resulting in values between 1 and 5 for each scale. Higher scores represent higher congruency to the CCM. Descriptive analysis included mean and standard deviation. The intracluster correlation coefficients (ICCs) for each PACIC-5A scale were calculated to estimate the variation within the clusters and to choose the appropriate regression model.[20] After calculating

bivariate correlations, stepwise regression analyses were performed to reveal predictors of a high PACIC sum score and a high 5A score.

Results

1,021 (81.7%) of the administered 1,250 questionnaires were returned. An analysis of the non-respondents revealed no significant differences with respect to sociodemographic data, OA duration and comorbidities in comparison to patients who returned the questionnaires. Table 1 displays characteristics of the study sample. Women were overrepresented (66.0% of respondents): an effect most likely related to the prevalence of OA being nearly twice as high among women as among men. Mean duration of osteoarthritis was 14.9 (SD 14.3) years.

Table 1. Characteristics of the study sample separated by gender (n=1021)

	Gender			
	Male (347/34.0%)		Female (674/66.0%)	
	mean	SD	Mean	SD
Age	65.16	14.75	66.64	15.33
Body mass index (BMI; kg/m²)	28.39	4.26	28.12	5.16
Educational Level (1-5)	2.61	1.11	2.38	0.83
Duration of OA (years)	14.80	16.18	13.13	11.09
Married/Living in partnership	278	80.1 (%)	376	55.8 (%)
Quality of life (AIMS2-SF dimensions)				
Lower body	2.39	1.71	2.98	2.08
Upper body	1.38	2.33	1.54	2.22
Symptom	4.49	2.17	5.12	2.18
Affect	2.60	1.28	3.10	1.36
Work (126 women/89 men)	3.08	2.67	2.34	2.23
PHQ-9 score	15.33	4.76	15.95	4.63
Comorbidities	Total	%	Total	%
High blood pressure	181	52.1	384	56.9
Elevated cholesterol	124	35.7	245	36.3
Diabetes	57	16.4	120	17.8
CVD	62	17.8	70	10.3
Asthma/COPD	34	9.8	64	9.5

Table 2 shows the descriptive statistics of the individual scales of the PACIC-5A scores separated by gender. The average overall score of the PACIC was 2.79 (SD 0.83) in men and 2.67 (0.89) in women. There was adequate variability in the overall scale and all subscales as indicated by the standard deviation. Significant differences between men and women occurred in the “problem solving” scale of the PACIC and the “agree” scale of the 5A.

Table 2. Score distribution of the PACIC-5A

PACIC-Scale	Gender						p*
	Male			Female			
	Mean	SD	95% CI	mean	SD	95 % CI	
Activation	3.51	1.10	3.31-3.52	3.39	1.14	3.22-3.48	0.302
Delivery	3.34	0.84	3.20-3.46	3.33	0.92	3.18-3.38	0.851
Tailoring	2.41	0.88	2.26-2.54	2.31	0.95	2.17-2.40	0.294
Follow-up	2.39	1.02	2.16-2.52	2.29	1.02	2.15-2.41	0.370
Problem solving	2.94	1.15	2.71-3.13	2.62	1.21	2.44-2.81	0.009
PACIC sum score	2.79	0.83	2.64-2.93	2.67	0.89	2.53-2.76	0.185
5A Scale							
Assess	2.86	1.12	2.67-3.02	2.77	1.11	2.61-2.88	0.427
Agree	3.31	1.03	3.09-3.42	3.09	1.06	2.95-3.19	0.050
Advise	2.74	0.83	2.60-2.86	2.74	0.94	2.58-2.88	0.938
Assist	2.42	0.92	2.24-2.57	2.25	0.99	2.12-2.37	0.089
Arrange	2.17	0.98	1.92-2.28	2.10	1.01	1.97-2.22	0.492
sum score	2.79	0.84	2.64-2.93	2.65	0.89	2.53-2.73	0.131

* t-test

Correlations of the PACIC sum score and the 5A score to patient characteristics, PHQ-9 and AIMS2-SF scores are displayed in table 3. Notable correlations were found for age, educational level and the PHQ-9 score. Interestingly, the correlations for the AIMS2-SF scales were all statistically significant but, with the exception of the affect scale, quite low. All factors achieving significance were entered in the regression model.

Table 3. Correlations of patients variables with the PACIC and 5A sum score

		PACIC sum score	5A sum score
Gender**		0.099	0.109
Age (years)*		-0.322	-0.349
Educational level**		0.401	0.3.78
Marital status*		0.028	-0.099
Disease duration (years)**		0.184	0.178
BMI (kg/m²)**		0.213	0.199
No. of comorbidities**		0.145	0.177
PHQ-9 sum score**		-0.347	-0.421
AIMS2-SF	Lower body**	0.128	0.139
Scales	Upper body**	0.188	0.201
	Affect**	0.292	0.277
	Social**	0.144	0.156
	Work**	0.201	0.173

Level of statistical significance: *p<0.05; **p<0.01; (Spearman rho)

To decide which regression model would be appropriate we first calculated the ICCs of the PACIC-5A to estimate the variation between the different practices. Interestingly, the ICC was below 0.01. Consequently, we decided to choose a linear regression model without considering the cluster effect. Table 4 displays the results of the regression analysis with the PACIC sum score as dependent

variable. As can be seen, only two factors remained in the final model which explained 29.5 % of the variation in the PACIC sum score. The educational level was the strongest predictor with a beta of 0.421 (p<0.008), reflecting that a higher educational level predicted higher scores on the PACIC score. The relationship to age was inversely: higher age predicted lower PACIC sum scores, reflected in a beta of -0.319 (p=0.016). The PHQ-9 score was eliminated in the last step of the regression model while slightly surpassing the demanded significance level (beta=0.107; p=0.057).

Table 4. Predictors of the PACIC-score assessed by stepwise regression

Dependent: PACIC sum score Unadjusted R^2 = 0.302 Adjusted R^2= 0.295 F= 21.233; p<0.0001	beta	SE	T	p
Educational level	0.421	0.118	3.620	0.008
Age	-0.319	0.121	2.022	0.016

Interestingly, the regression model revealed similar predictors for the 5A sum score as for the PACIC score: age as a negative predictor of high 5A scores, and educational level as a positive predictor (table 5). Additionally, the PHQ-9 score remained as significant predictor in the final model. Higher PHQ-9 scores were associated with lower 5A scores.

Table 5. Predictors of the 5A score assessed by stepwise regression

Dependent: 5A sum score Unadjusted R^2 = 0.312 Adjusted R^2= 0.302 F= 21.455; p<0.0001	beta	SE	T	p
Age	- 0.386	0.145	3.450	0.004
Educational level	0.344	0.129	1.988	0.002
PHQ-9 score	- 0.288	0.243	1.874	0.005

Discussion

The CCM has been promoted as a template of care for the chronically ill, aiming to substantially improve quality of life.[4,21] Our study showed that certain patients rated those aspects of their care more favourably that were consistent with the CCM. Being younger, better educated and less depressed increased the chance to achieve higher scores on the PACIC-5A. Assuming that the PACIC-5A reflects the accordance of physicians' behaviour with the CCM, these patients are more likely to receive care that contains the core elements of chronic care such as activation, support, goal setting, assistance and frequent follow-ups.

Tsai et al. showed in their meta-analysis that interventions containing at least one CCM element could improve clinical outcomes as well as patient-relevant outcomes.[22] They included 112 studies, assessing diabetes, asthma, chronic heart failure and depression. Furthermore, a number of studies are available to date, that focused on implementing at least a few elements of the CCM. The results emphasise that the CCM is not only a theoretical framework that improves process parameters as well as patient-relevant outcomes, in a recently published study, Vargas et al. could also show that the CCM approach can reduce risk factors for a heart disease in diabetes patients.[23] Regarding chronic obstructive pulmonary disease Adams et al. reported in a recent review that patients who received interventions with two or more CCM components had lower rates of hospitalisations and emergency/unscheduled visits and a shorter length of stay in a hospital compared with control groups.[24] It has to be considered, though, that most of these data were retrieved in hospital settings or HMOs and cannot easily be transferred to primary care settings. So far, only one study is available showing that CCM elements can be implemented in small independent practices and result in improved care for diabetics.[25]

Our paper has three main findings. First of all, the comparison of the scores of our study sample with previously collected data suggests that current care for patients with OA reflects the key elements of the CCM only poorly. Glasgow et al., for instance, found notably higher values among diabetes patients than we did: their reported means in the “tailoring/goal-setting” scale (3.1 in men and 3.0 in women), in the “follow-up” scale (2.9 in men and 3.0 in women), and the “problem-solving” scale (3.4 for both gender) do not even fall within the 95% CIs of our outcomes.[12] The same result applies to the sum score (3.2 in men and 3.2 in women). The results regarding the 5A-approach are quite similar, with notably lower scores regarding all scales of the 5A part of the PACIC-5A.

In our opinion, there are several reasons that account for the significantly lower scores in our study: first of all, Glasgow collected his data in an HMO and not, as we did, in a primary care setting with a large number of single handed practices. Furthermore, and related to the first reason, care according to the CCM is proactive, focused on activating, involving and accompanying the patient. This kind of care frequently requires the involvement of qualified practice nurses or physicians’ assistants. But these medical professions are currently not available in Germany.[26] Another important reason may be the observed disease itself. It could be assumed that physicians’ engagement in diseases such as diabetes, heart insufficiency or depression is higher than in OA, which is regarded as less

threatening to the patients' health, or at least associated with a lower burden of disease.[27]

The second important finding is that the PACIC as well as the 5A scores are not correlated with severity of OA. None of the AIMS2-SF scales, reflecting different aspects of quality of life of OA patients, was significantly correlated with the PACIC or the 5A scales, and none of them remained in the regression model. This suggests that GPs counselling efforts are not dominated by the disease itself.

The most important finding is related to the predictors of high PACIC and 5A scores. The finding that younger, better educated patients with lower PHQ-9 scores are more likely to achieve high scores on the PACIC-5A could reflect differences in physician behaviour towards different patient groups as well as the fact that these patients are more actively seeking care that complies with the CCM. Still, this association cannot be concluded from our data and remains speculative. Nevertheless, this information is valuable since it may suggest that in implementing the CCM or its elements, it will be of great importance to assure that all patient groups are able to benefit to the same extent from this advance in chronic illness care. It is well known that most chronic diseases such as diabetes and high blood pressure are associated with social status[28,29]; a recent German health survey confirmed the association of chronic conditions and social status once more.[30] It is quite obvious that these patients would benefit the most from advanced approaches like the CCM. Our data suggest that efforts in implementing CCM elements should consider to assure that these patients will eventually benefit from the CCM as well as other patients.

Since Glasgow et al. could not reveal significant differences in the PACIC scores regarding gender, ethnicity, income and comorbidities, it will also be of great importance to consider the setting in which the data were collected[9,12]: Their patients were enrolled in an HMO; ours in a primary care setting.

Strengths and weaknesses

There are some weaknesses in our study which should be acknowledged: first of all, the assumed linkage between different PACIC scores and differences in received care has not been proven empirically. But preliminary data from a nationwide research project using the PACIC-5A in evaluating diabetes disease management programs confirm this assumption. Secondly, the data were derived from a cross-sectional observational study within a sample of OA patients and it remains unclear whether the findings can be transferred to other diseases and patient groups. Furthermore, the social situation of participants could not be

assessed properly since it is still problematic in Germany to ask for the annual income. Since uninsurance is no problem in Germany and the health care system can be freely accessed by everyone this weakness may be limited. The strength of this study is its reasonably large and representative sample of primary care practices and patients. In contrast to previous studies, which assessed the congruency to the CCM by a health professionals' perspective (by means of the Assessment of Chronic Illness Care (ACIC) [31]), we assessed it from a patients perspective.

Conclusion

Without a doubt, the framework of the CCM represents an important step towards an improved care for the chronically ill. Our findings suggest that currently this structured approach is only rarely implemented in the care for patients with OA in a primary care setting. The finding that younger and better educated patients are more likely to receive care which complies with the CCM suggests that the implementation of CCM or CCM elements in primary care will be challenging in order to assure that all patients benefit equally. Further research is needed to confirm our results and assess possible implications for implementing the Chronic Care Model in primary care.

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Chapter 10

How can the practice nurse be more involved in the care of the chronically ill? The perspectives of GPs, patients and practice nurses

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Background

In Germany medical care in the primary care setting is provided exclusively by a physician, the GP. In a normal medical practice several practice nurses support the physician in mainly administrative aspects such as arranging appointments for patients, answering telephone calls, preparing and providing the patient files and so on. However, technological and/or societal changes, especially those concerning the health care system, are stimulating considerations of expanding nursing roles in Germany. For example, due to the big problem of recruiting prospective candidates, especially in primary care, the number of GPs in Germany will drop tremendously in upcoming years. In some rural areas, especially in the eastern part of Germany, it is already very difficult to find young GPs willing to work there. Additionally, the workload is increasing due to administrative work. The newly introduced disease management programs (DMPs) have again boosted this trend. This aggravation of labour conditions has started a fatal circle: more and more German physicians are leaving the country, mostly to work in the U.K. or Scandinavian countries where they find better working conditions[1,2]. Thus, these developments force physicians and policymakers to consider new models of nurses' involvement.

In other countries, different health care professionals are involved in patient's care. In the U.S., for example, from the 1960s onwards, physicians assistants were established, providing care together with nurses and nurse practitioners[3,4]. There is very little equivalence in education and roles across borders. Different roles of nurse practitioners (NP) and physician assistants (PA) exist in different countries.

In the United States both of these roles generally require graduate education involving intensive study in diagnostic methods and therapeutics. However, several studies showed that involvement of medical assistants improves patient care or quality of life, even if the involvement contained simple procedures as for instance frequent contacts by telephone[5,6]. Therefore, the number of assistants increased constantly in the primary care setting in Canada as well as in the U.S.

Contrary to the U.S. and Canada, little is known about the involvement of doctors' assistants in the care of patients in Germany. GPs are complaining about an increasing workload so that increased involvement of doctor’s assistants could reduce the workload and help them concentrate on patients. Especially, chronic diseases with frequent consultations and less change in therapy could be possible domains where an increased involvement of practice nurses decreases GPs' workload and increases patient satisfaction[5]. Chronic diseases often require knowledge on coping strategies as well as information on strategies to prevent

further deterioration. This is reflected in the Chronic Care Model (CCM), a conceptual framework for delivering care for chronically ill, which has received widespread acceptance. However, the implementation of the CCM requires a team approach, i.e. heightened involvement of practice nurses in patient care.
It seems that the time is right to consider a new breed of healthcare professionals who could take on many of the tasks currently undertaken by doctors, and therefore enable the physicians to concentrate on their original duty: providing medical care.
The aim of our study, therefore, was to assess the present involvement of practice nurses in patient care, to estimate possible areas of heightened involvement and to reveal existing barriers by exploring the perspectives of all groups involved in the treatment process: patients, GPs and practice nurses.

Methods

We chose a qualitative approach because little is known about involvement of practice nurses in the care of chronically ill patients. So far, there has been no German study on this topic.

Sample

The selected GPs, assistants and patients represented a stratified sample regarding gender, city and rural population living in Heidelberg and surrounding areas[7]. The GPs were to have a minimum of 5 years' experience; the practice nurses were required to have a minimum of 10 years' professional experience. The patients were selected at random from the GPs' computer files. They had osteoarthritis as primary chronic disease, and all of them had at least one additional chronic disease such as diabetes, heart insufficiency or hypertension. During their practice visit the GP asked whether they were willing to participate in an interview. All patients but one agreed to take part in the study. Written consent of all participants was obtained. The study was approved by the ethics committee of the University of Heidelberg; approval number 019/2004.

Interviews

The interviews were conducted during the summer of 2004. The GPs and assistants were interviewed in their respective practices; the patients were interviewed at home by a trained interviewer. After a detailed study of the literature regarding patients' perspectives on chronic diseases, we compiled open-question interview guidelines. In order to have the possibility to compare the views of GPs,

patients and practice nurses, we matched the interviews for the three groups on important issues but also asked specific questions concerning the investigated group only.

The questions focused on the following aspects:
- Actual areas of practice nurses' involvement
- Main obstacles regarding more involvement
- Possibilities to overcome the obstacles

Following the regular process of care, these aspects were assessed in the following areas:
- diagnostic procedures, examinations and treatment
- advice giving/counselling
- referrals

During the interview the interviewer ensured that every aspect was explained sufficiently and in detail, so that no questions or misunderstandings remained.

Data analysis

The interviews were recorded digitally, transcribed literally and analysed by four different researchers with ATLAS.ti -Software[8]. In advance, a categorising system had been established based on the interview guidelines. In order to achieve maximum objectivity, all interviews were read by all researchers and categorised independently. The categorising system was consequently modified after agreement had been obtained among all four researchers. Numerous free categories were developed from the text, discussed and adjusted so that they were as similar as possible in all three interviewed groups, since the objective was to compare the different perspectives of the groups.

Results

Although the interview guidelines for all groups contained the same number of questions, the interviews differed in length depending on the group; the GPs' interviews being the longest, and the assistants' interviews being the shortest (table 1). The categorical systems with subcategories are displayed for each interviewed group in tables 2, 3, 4. The numbers in brackets display how many participants responded to the respective category.

Table 1. Baseline characteristics of the study sample

	Practice nurses	GPs	Patients
N	20	20	20
Mean age (range)	41.3 (29-56)	43.5 (33- 57)	56 (40-78)
Years of working experience in general practice (SD)	13-35 (21.7)	8-19 (11.3)	
Longest duration of chronic disease (Mean/(SD))			17 (9.3)
Number of chronic diseases (Mean/(SD))			2.9 (1.1)

Involvement in diagnostic procedures, examinations and treatment

GPs considered it adequate to delegate simple routine examinations, for instance, the measurement of blood pressure or the measurement of height and weight to the practice nurses. They assumed that patients would accept practice nurses to perform only these examinations. Taking a blood sample was appraised quite differently: some GPs regarded it as alleviation; some preferred to take the blood themselves. The main reason for these differences was not an assumed lack of knowledge or skills, but rather the GPs' preferences with respect to the proceedings in the practice.

> *"I prefer to take the blood myself; I can already start talking to the patient.....Sometimes I get the most important information during this procedure"* GP 7

All GPs said that it is their duty to perform the examination, to inform the patient and explain diagnosis, prognosis and therapy. Most GPs were convinced that examinations, the following explanations and counselling represent one of the main challenges in primary care and that this can only be done by the physician. A lack of medical knowledge was also mentioned as an important obstacle against a broader involvement of the practice nurse in this area. The third most frequently named obstacle was that GPs are convinced that patients expect to be informed about diagnosis, prognosis and therapeutic options only by the physician.

> *"To inform the patients that's only my job. That's also what the patient expects. They would never accept that the practice nurse tells them what's going on with them." GP 17*

Table 2. Categorical system with first subcategories (General Practitioners)

Main categories	First subcategory
Present situation (20):*	• Involvement in medical proceedings (6) • No involvement in medical proceedings (14)
Team approach in general (20):	• Imaginable (18) • Not imaginable (2)
Barriers / Problems (20):	• Lacking (medical) knowledge/skills (19) • Workload (16) • Perceived lack of patients' acceptance (14) • Fear of worsening physician-patient-relationship (12) • Lack of reimbursement (5) • Doubt about efficacy of increased involvement (5) • Lacking motivation by practice nurses (2)
Possible tasks for practice nurses in the context of team approach (20):	• Hand out patient information leaflets (12) • Lifestyle counselling/advice giving (11) • Arranging/Assisting referrals (5) • Others (4)
Possibilities to overcome the obstacles (12):	• Better education for practice nurses (11) • Reimbursement (5) • Offers of training for practice nurses (2)

* numbers in parentheses are the frequency of subjects who said something relating to the respective category

Most patients found the practice nurse to be skilled enough to measure the blood pressure, blood sugar and also to take i.v. blood samples. Information about the disease itself, the prognosis and possible treatment options were very important to patients. In accordance with the assumption of the GPs, they expected to receive important information about their disease only from the physician. They assumed that the practice nurses do not have the knowledge to inform them about the causes and prognosis of the disease. Moreover, it was very important to the patients that they can always talk directly to the GP about their concerns without having to explain the requests to the practice nurse first. With respect to treatment, many patients seemed to assume that the practice nurse is familiar with possible treatments beyond the evidence based procedures. Many patients assumed that the practice nurses have an overview or knowledge about treatments that had been beneficial for other patients. The practice nurse was regarded as a source for additional treatments which are beyond regular treatment procedures.

> *"Well, I do sometimes ask the practice nurse, if she knows something which may have helped other patients, some sort of cream or something, which maybe the doctor can't prescribe." P3*

Practice nurses stated that they are not asked about the diagnosis or prognosis of diseases by the patient. They complained that their schooling focused more on administrative things than on medical knowledge. Due to this, they did not feel competent to say anything about the disease, its cause, possible influences on the progression, the treatment and prognosis. The knowledge they have on these aspects is mostly acquired by working experience and not by schooling. Patients rarely questioned the practice nurse regarding medication. Formal matters such as equivalence of medications with different names etc. were a matter of concern. The practice nurses did not consider themselves competent enough to talk about medication and often refered to the GPs' instructions. All of them desired to receive more medical information during their education, but nevertheless, they clearly stated that providing this information to the patient is up to the GP. Practice nurses' statements were in line with patients' statements: most of them confirmed that they were frequently asked about additional treatment options which are beyond the classical treatment as for instance possibilities to support a lifestyle change, supplements, etc.

> *"Patients often ask me: do you know somebody who had positive experiences with this or that.....sometimes I wonder why they don't ask the doctor about that, but it seems that they feel ashamed to ask the doctor about this, especially the older ones." N 10*

> *"Sometimes I ask the patient if he mentioned the problems to the doctor during the consultation, but the patients often reply that the doctor is too busy and that they don't want to bother him with their complaints too much, because there's no real effective relief anyway."* N 19

Involvement in counselling

As shown in the interviews, advice giving or some sort of counselling by the practice nurse was acceptable for the GPs mainly in the fields of "lifestyle-change", "nutrition" and "motivation for physical activity". Advice concerning medical issues such as pharmacological treatment or other specific treatments is regarded to be solely the GPs' responsibility. Moreover, as GPs indicated, the involvement of practice nurses is only possible in the context of group education for patients, whereas individual guidance is rejected for financial and time reasons. In the context of DMP's such educational groups for patients have been implemented in

many medical practices. However, some GPs were ambivalent concerning group education for patients.
Some doubted their efficacy, others criticised that it is too time-consuming, or that some practice nurses are not motivated enough.

> *"These diabetes education groups are quite all right, but what if even more DMPs will be implemented? Should the practice nurse educate patients all day long then?"* GP6

> *"...you can communicate that to younger practice nurses, but that doesn't work with older assistants, they just don't regard it to be their duty..."* GP13

Most of the GPs found it acceptable that practice nurses hand out patient information leaflets, or point out contacts such as self-help groups. However, some GPs indicate that this kind of patient care is already beyond their field of duty.

> *"She can't assess what is good for the individual patient, and I don't think it's good if the task is handed down to the next level..."* GP 10

> *"We can't coordinate patients' sports activities."* GP14

All practice nurses found involvement in counselling, for example in the context of DMP, to be an appreciation of their work and a diversion from administrative tasks which constitute their daily routine. Some practice nurses objected that they are only insufficiently qualified for advice giving which highlights the importance of high quality education for practice nurses. Education programs in the context of DMPs seem to attend to this aspect insufficiently.
Patients were mainly positive about educational groups and thought that the practice nurse is competent to offer such groups. In addition, most patients would like the practice nurses to hand out printed information and provide knowledge about self-help groups, community-based or other local offers. They regarded the practice nurse to be a more adequate source for this kind of information than the GP.

Table 3. Categorical system with first subcategories (Patients)

Main categories	First subcategory
Team approach in general (20):*	• Imaginable (19) • Not imaginable (1)
Barriers / Problems (20):	• Lacking (medical) knowledge (11) • Fear of worsening physician-patient-relationship (2) • Others (4)
Possible tasks for practice nurses in the context of a team approach (13):	• Organising education groups (10) • Giving information about referrals (specialists) (4) • Asking patient about his mood (2) • Talking to the patient sympathetically (1)

* numbers in parentheses are the frequency of subjects who said something to the respective category

Involvement in the referral process

Concerning the referral process, the GPs delegate many steps in the process to the practice nurses, e.g. filling in the referral form or making an appointment in case of urgent referral. The practice nurses were responsible for the administrative part of the referral. Some GPs generated lists of specialists, which the practice nurses hand out to the patients.

Practice nurses indicated that patients often ask them about recommendable physicians regarding criteria such as localisation, friendliness and short waiting times. Even if lists with specialists are handed out to patients, they often asked for personal recommendations.

> *"Especially older patients appreciate it when we show them on the map how they can get there or which bus to take."* N 5

Patients did appreciate getting information about specialists they can consult. Particularly when the GP does not explicitly recommend a specialist, patients contacted practice nurses because they have a lot of information.

> *"...it's not that easy to walk anymore, and I'm really glad when they tell me about an orthopaedist I can go to and reach easily."*

Table 4. Categorical system with first subcategories (Practice Nurses)

Main categories	First subcategory
Present situation (20):*	• Involvement in medical proceedings (3) • No involvement in medical proceedings (17)
Team approach in general (20):	• Imaginable (20) / Wish of being more involved (18) • Not imaginable (0) / No wish of being more involved (2)
Barriers / Problems (20):	• Lacking (medical) knowledge/skills (20) • Workload (17) • Perceived lacking patients' acceptance (1) • Others (4)
Possible tasks for practice nurses in the context of a team approach (15):	• Giving information on local offers, self help groups, etc. (13) • Calling the patient in regular intervals (i.e. case management) (7) • Motivating the patient to use self-help groups and social contacts (3) • Organising (self-help) groups (2) • Exchanging information about patient with GP (2)
Possibilities to overcome the obstacles (19):	• Improved medical education (14) • Changes in practice organisation (11) • More support by GP (3) • Training offers for practice nurses (2)

* numbers in parentheses are the frequency of subjects, who commented on the respective category

Discussion

In German practices, there is only one kind of assistance for the GP: the practice nurse. As our findings showed, practice nurses are currently only rarely involved in diagnostics and treatment, and are mainly occupied with administrative tasks. The DMPs as performed in Germany can be regarded largely as management by protocol, meaning that they do not require extensive physicians' involvement. Therefore, since the implementation of DMPs, many practice nurses are more involved in giving patients' advice, which most of them do appreciate.

Patients as well as most of the GPs are positive about this involvement. The growing role of disease management programs have led to considerations regarding nurses' broader involvement in the care of the chronically ill. For most of these patients the diagnostic phase is largely over, meaning that the more technically sophisticated and often more lucrative phase of care has passed - the "threat" to physicians is minimal. Furthermore, the great deal of time-consuming patient teaching involved in the care of chronically ill patients in maintenance care is believed to "come naturally" to nurses as a result of their education. Additionally, patient teaching can be done in a cheaper way by nurses, thus liberating physicians for "more complex" care.

Major barriers for further integration into care according to practice nurses are professional deficits stemming from a lack of medical contents in their education. Therefore, the continuous training of practice nurses is of great importance.

However, with regard to further training, the study showed that there is still a lot of room for improvement quantitatively as well as qualitatively. Regarding physicians our results also indicated that the expansion of roles will only work if physicians do not feel threatened by the shift of territory and responsibility; when they believe that heightened involvement of nurses leads to advantages such as easier workload and happier patients, and are confident concerning nurses' competence. Moreover, the study showed that the role of the practice nurse in Germany is very different compared to the role nurse practitioners or physicians' assistants have, for example, in the US or Canada where they are an essential part of care[9]. This is a prerequisite for the implementation of new treatment approaches as for instance the Chronic Care Model (CCM). The CCM is a recently developed conceptual framework for the care of chronically ill patients, which favours planned and proactive care[10]. Due to the complex approach of care in this model it cannot be performed by the physician alone, but requires a team approach[11,12]. Moreover, the wish of patients for more information will increase further[13,14] and resources on the GPs' side will decrease[1]. Thus, in the near future, it seems inescapable to spread care, which is, as our findings showed, problematic since until now practice nurses in Germany are only marginally involved in patient care.

Even by delegating simple tasks nurse-delivered interventions can improve patients QoL and reduce costs[15,16]. Practice nurses' involvement can therefore range from regular telephone contacts, which reduce costs and heighten patients' satisfaction to more specialised fields of care[17,18]. Consistent with our results other studies show that practice nurses would appreciate an upgrading of their work within a more team oriented approach[19].

Our study has some weaknesses, e.g. the relatively advanced age of the patients as well as their low level of education. Older people tend to be happier with their GPs[14,20], which could be one of the reasons why we did not get so many concrete suggestions for improvement from patients. A further weakness is that we did not mention ideas for improvement or interventions in the interview guide. Although this was discussed beforehand, we abandoned the idea in order to keep answers as open and honest as possible.

Despite these limitations, to our knowledge, our study is the first to consider individual perspectives of patients, GPs' and practice nurses regarding involvement of practice nurses simultaneously. The interview guidelines were

developed interdisciplinary, i.e. in cooperation with a psychologist in order to ensure appropriateness for patients with chronic illnesses. Furthermore, four researchers assessed and categorised the qualitative data independently according to stringent guidelines, in order to achieve the highest possible objectivity[7,21].

Conclusion

In conclusion, higher qualification of practice nurses could contribute to a reduction of GPs workload. This requires qualitatively improved education and further training for practice nurses[22], which would lead to an appreciation of the profession in return. Our study showed that the majority of patients would accept the practice nurse as a competent part of the care team and that GPs' skepticism is often the main problem with regard to involvement of practice nurses. This however, will leave an important resource unused and will widen the gap between the German health care system and more team-oriented systems.

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Chapter 11

Case management of arthritis patients in primary care: a cluster-randomised controlled trial

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Abstract

Objective: To assess whether providing information on arthritis self-management through general practitioners (GPs) increases the quality of life in patients with osteoarthritis and whether additional case management provided by practice nurses shows better results.

Methods: We conducted a pragmatic, cluster-randomised, controlled, 3-arm trial that included 1,021 patients from 75 primary care practices in Germany. GPs were randomised to intervention group I, group II or a control group. GPs of both intervention groups participated in two peer group meetings. In intervention group II, additional case management was conducted via telephone by a practice nurse. The primary outcome was change in quality of life, assessed by the German version of the Arthritis Impact Measurement Scales Short Form (AIMS2-SF). Secondary outcomes were health service utilisation, prescriptions and physical activity. Data were controlled for depression using the Patient Health Questionnaire 9 as a potential confounder.

Results: Of 1,125 administered questionnaires, 1,021 were analysed. Compared with the control group, no significant changes occurred in intervention group I with respect to the primary outcome. Performed radiographs decreased significantly (P=0.050), whereas prescriptions of acetaminophen increased significantly (P < 0.001). In intervention group II, significant changes in the AIMS2-SF dimensions social (P < 0.001), symptom (P=0.048) and lower body (P=0.049) were identified. Radiographs (P=0.031) and orthopedic referrals (P=0.044) decreased whereas prescriptions of pain relievers increased significantly.

Conclusion: Improving the quality of life in patients with arthritis using arthritis self-management seems challenging. Simply providing this information through GPs is not sufficient, but combining it with case management seems to be a promising approach.

Introduction

Osteoarthritis (OA) is highly prevalent in the population and its prevalence is expected to increase in coming years.[1] OA has a substantial impact on patients' quality of life (QOL), as it is frequently associated with pain and disability. Because some of the factors that affect the course of OA such as body weight[2] and physical activity[3] are receptive to influence, programs such as arthritis self-management programs (ASMPs) or the Program for Rheumatic Independent Self Management[4] have been developed. Besides recommendations for physical activity and weight loss, these programs aim at increasing patients' ability to handle the disease by increasing self-efficacy. However, their effects, at least in patients with OA, seem to be weak as a recent meta-analysis of self-management programs for certain chronic diseases has indicated.[5] To date, these programs generally have taken place outside of medical care settings[6], but a recently published study by Buszewicz et al. indicated that ASMPs may have no substantial impact on QOL of primary care patients.[7]

However, because the main care provider and primary contact person for most patients is the general practitioner (GP), it seems appropriate to evaluate interventions in a primary care setting.[8] Programs such as ASMPs, which require participation in courses, are always subject to compliance problems. Because patients visit their GP for many reasons, and information on arthritis self-management can be more easily and frequently provided during these visits than through courses, it would seem a worthwhile challenge to train GPs to provide this information. However, implementing interventions in a primary care setting creates several problems.[9,10]

In Germany as well as in many other European countries peer group meetings (quality circles) of physicians are a well-established concept, and several studies have proven their impact on different outcome parameters such as on prescriptions.[11] Peer group meetings are characterised by a small number of participating physicians, usually less than 15, and by intense discussion among participants. Furthermore, recent studies have shown that case management is a promising approach to improving care for the chronically ill[12], because it enables a structured follow-up which has been shown to be an important issue.[13] Case management has been defined as "taking responsibility for following-up patients; determining whether patients were continuing the prescribed treatment as intended; assessing whether [...] symptoms were improving; and taking action when patients were not adhering to guideline-based treatment, or when they were not showing the expected improvement".[14]

The goal of our study was to evaluate whether providing information on arthritis self-management through GPs can increase patients' QoL. Because prior research has indicated that case management is a promising approach to the treatment of chronic diseases, we assessed whether additional case management by the practice nurse shows better results than involving GPs only.

Patients and methods

The study was designed as a pragmatic, cluster-randomised, 3-arm intervention study, which is considered an appropriate approach when assessing implementations in a primary care setting.[15] The study protocol was approved by the ethics committee of the University of Heidelberg prior to the start of the study. The study was conducted in accordance with medical professional code and the Helsinki Declaration (1996) as well as the German Federal Data Security Law.

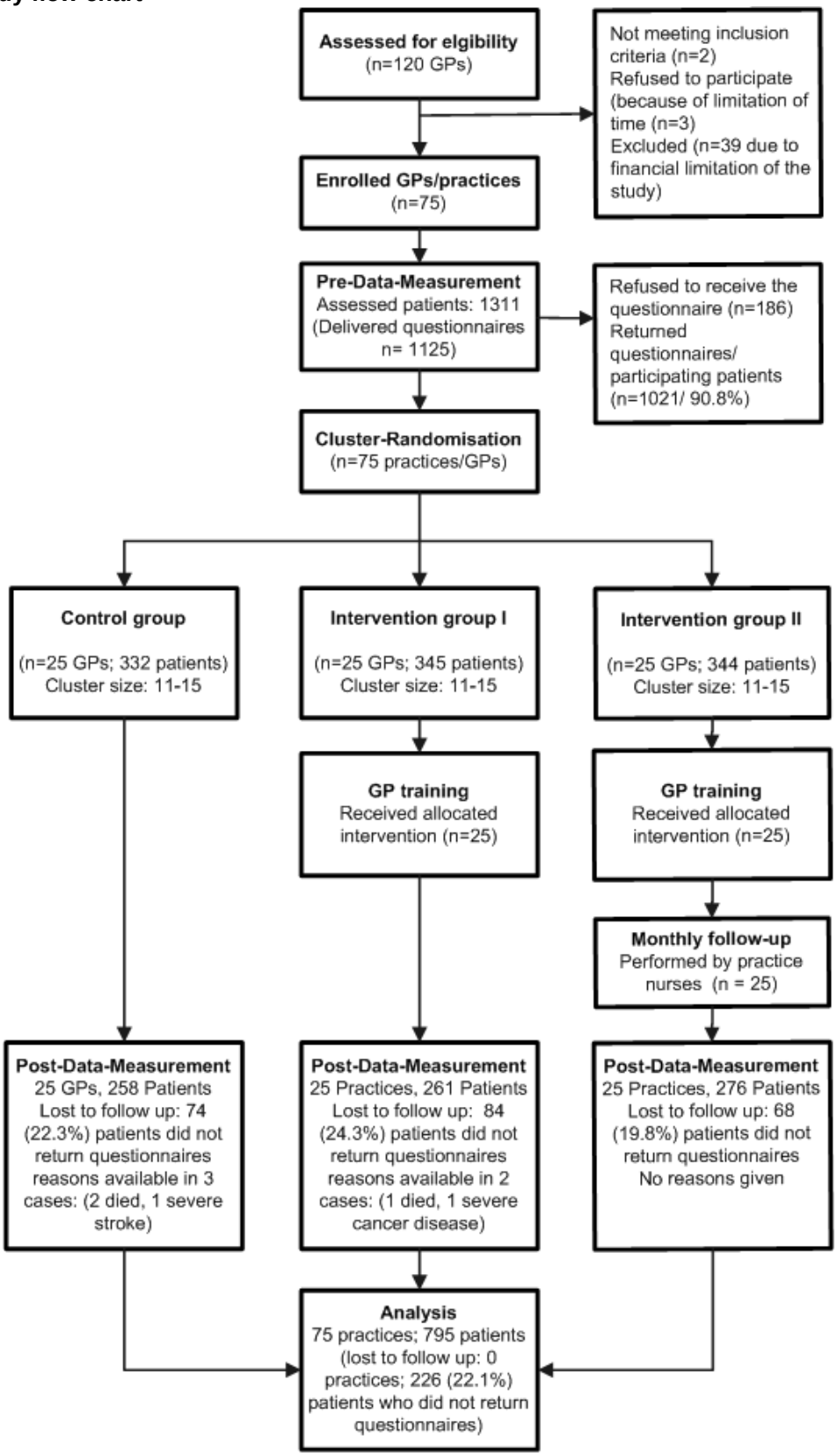
Recruitment of GPs

As displayed in the flowchart (figure 1) created according to the Consolidated Standards of Reporting Trials (CONSORT) group (http://www.consortstatement.org), 503 GPs in the areas of Baden-Wuerttemberg and Bavaria were invited to an information meeting regarding the study with a formal letter from the Department of General Practice and Health Services Research of the University of Heidelberg.

Patient inclusion criteria

To be eligible for inclusion patients had to be aged ≥ 18 and diagnosed with OA in the knee or the hip according to the American College of Rheumatology criteria.[16,17] Patients were contacted in consecutive order of appearance in the medical practice: if the main reason for the current encounter was related to OA. After giving their written informed consent patients received the questionnaire and a stamped envelope with the postal address of the university to enable them to return the questionnaires directly. The questionnaires for post-intervention evaluation were sent to the patients by mail. Written reminders were used and GPs were also asked to remind patients to return the questionnaires. Patients were explicitly informed that neither the GP nor the practice team had any way of gaining knowledge of their answers.

Figure 1. Study flow chart



GPs=general practitioners

Primary and secondary outcomes and assessment instruments

The primary outcome was QoL, assessed by the Arthritis Impact Measurement Scales Short Form (AIMS2-SF), an internationally validated instrument for the assessment of QOL in patients with arthritis. Secondary outcomes were physical activity, assessed using the short form of the International Physical Activity Questionnaire (IPAQ); health service utilisation (encounters with GPs, orthopaedics, or nonmedical practitioners of alternative medicine; number of physiotherapy sessions, radiographs, surgical interventions, injections to the joint) and prescriptions. Specialist care for patients with OA in Germany is provided by nonsurgical orthopedics, and not by rheumatologists as in many other health care systems.

Referral rates to these orthopaedics are very high as are the number of radiographs.[18] We hypothesised that referral rates and number of radiographs would decrease.

To assess physical activity, we used the short form of the IPAQ.[19] The IPAQ was developed by an international panel of experts and validated in nine European countries, including Germany. Energy expenditure related to physical activity (metabolic equivalents, minutes/week) was calculated according to the IPAQ recommendations (available at http://www.ipaq.ki.se). It is known that depression aggravates the pain associated with OA and contributes considerably to the disability.[20] Furthermore, prior analyses have demonstrated that depression is particularly frequent among patients with OA.[21] Because depression could have a negative influence on the effect of the intervention it was assessed by means of the Patient Health Questionnaire (PHQ-9)[22] to enable it to be controlled as a potential confounder. We also assessed the following chronic conditions as comorbidities: high blood pressure (>140/90 mm Hg), diabetes, chronic heart failure, coronary vessel disease, elevated cholesterol level (total cholesterol >200 mg/dl), ulcer or stomach disease, asthma/chronic obstructive pulmonary disease, renal insufficiency, (prior) cancer and (prior) stroke. The baseline assessment was conducted in April 2005, before any intervention was performed. The group meetings with the GPs took place from the end of April until the end of June. The post-intervention assessment was completed in December 2005, 6 months after the last group meeting, and 9 months after the baseline assessment.

Sample size

Sample size calculations for cluster-randomised trials differ from sample size calculations for common randomised controlled trials and require, due to the

cluster effect, larger numbers of patients to achieve the same power as trials randomised on the individual level.[23] Based on the main outcome parameter (QOL) and the main outcome-assessment instrument (German version of the AIMS2-SF)[24] we performed a power calculation with the Cluster Randomisation Sample Size Calculator, version 1.02 (University of Aberdeen, Aberdeen, UK): assuming a minimum detectable difference between groups of 10% (as being clinically relevant), an intracluster correlation coefficient (ICC) of 0.03 (based on results from comparable studies in primary care[25]), a power of 90% and a significance level of 0.05. Assuming a dropout rate of 10% we had to include 25 medical practice; each including 14 patients at most. Because the characteristics of the clusters were already recognised when planning the study we aimed at minimising some important factors that had the potential to decrease significance or bias the cluster design: 1) we stratified the selected medical practices according to the variables rural/urban, and 2) instead of including a large number of patients per medical practice, we enrolled a large number of medical practices and allowed only 15 patients per medical practice to decrease variation in cluster size.

Intervention

The intervention was developed using a stepwise approach according to the recommendations of Campbell et al.[26]; including qualitative pre-studies to reveal the needs of doctors and patients as well as possible obstacles to implementation.[27] We also conducted a pilot study to test the assessment instruments, and to reveal possible barriers to their implementation.[28] After each step assessment tools and the intervention were reconsidered and refined in a consensus process including GPs and self-help groups. The intervention was multifaceted, because prior research demonstrated that strictly educational interventions with GPs were less effective. GPs in intervention group I participated in two interactive peer group meetings of 8 hours each. These meetings focused on three main issues: the evidence-based treatment of OA in a primary care setting; arthritis self-management programs for patients and the provision of motivational skills for working with patients, according to the 5-As approach (ask, advise, agree, assist, and arrange).[29] In addition to the meetings GPs received a written summary of evidence-based treatments for OA in a primary care setting. This summary contained the recommendations of the European League Against Rheumatism (EULAR) group for the treatment of OA and information provided by the German Medical Association.[30–32] Furthermore, GPs received written material for patients: a leaflet providing information about the cause, and the treatment

options as well as coping strategies. The leaflets also contained contact addresses for the two largest self-help groups, the German League against Rheumatism (*Deutsche Rheuma-Liga*) and the German Osteoarthritis Help Foundation (*Deutsche Arthrose- Hilfe*), for the patients. GPs also received booklets and audio CDs with a detailed exercise program, similar to some ASMPs, and were asked to provide these materials to every included patient. GPs in intervention group II participated in the same meetings so that all GPs received the same information.

Implementing case management

In an add-on approach practice nurses from intervention group II also participated in a course. During this course, the nurses were trained in case management. They learned about OA, how to call patients and monitor treatment using a structured OA-specific telephone questionnaire. The questionnaire assessed 3 dimensions of treatment in 11 items: pain, effects and side-effects of prescribed drugs and adherence to the GPs' recommendations regarding physical activity. Patients' answers were grouped into 3 predefined categories based on urgency of the given information: immediate GP referral, information forwarded to the GP after the telephone call and information forwarded at the end of the day. The categories were additionally displayed by green, yellow and red flags on the questionnaire. For example, if a patient reported acute stomach pain this information was marked with a red flag, and the patient was immediately referred to the GP. This stepwise procedure assured that the information was forwarded to the GP according to its urgency. Telephone monitoring started after the baseline assessment in May 2005 and ended in mid November, before the follow-up assessment. The telephone calls were conducted at least every 4 weeks.

Data collection and analysis

Each patient's set of questionnaires was linked to the GP's list via an identification number so that data given by the patients could be crosschecked with the patients' file. Information on patients' medication and health care utilisation was checked by 1 of 3 research assistants visiting each medical practice. This was done to estimate the reliability of patients' answers for a subsequent part of the project. If differences occurred, data from the medical file were used. Prescriptions were assessed via the Anatomical Therapeutic Chemical classification system code, and recalculated and displayed in defined daily doses (DDD) according to the recommendations of the World Health Organization (WHO; available at www.whocc.no/atcddd/). The DDD is the assumed average maintenance dose per

day for a drug used for its main indication in adults. Non-respondents were identified by comparing the questionnaires received with the GP's list of patients who were invited to participate. Sociodemographic data (sex, age, ethnicity, education level, work situation, family situation) were collected. Education level was defined as follows: 1 = elementary school or less, 2 = high school and 3 = tertiary degree or higher.

Statistical analysis

A flowchart, in accordance with the CONSORT statement for cluster-randomised trials, was created to give an overview of the involvement of practices and patients throughout the trial. Analyses followed a pre-specified plan, taking into account the cluster design. Descriptive statistics for baseline characteristics were displayed. Baseline data were compared using Student's t-test, or chi-square test for categorical data. In the case of missing data, the last observation carried forward method was used. If analyses of cluster-randomised controlled trials are performed on the patient level, the hierarchical structure has to be taken into account. To do so, we used the MLwiN package (Centre for Multilevel Modelling, University of Bristol, Bristol, UK). Following the recommendations of Campbell et al.[33] we initially calculated the ICC for each specific variable based on the baseline data of all patients. This ICC was used in the analyses later on. Change in the means of both intervention groups was compared with the change in the means of the control group using analysis of covariance (ANCOVA). All analyses were performed based on intent-to-treat, regardless of whether patients really received the intended treatment, and post hoc correction for multiple testing (Bonferroni) was implemented.

Results

Of the 503 invited GPs, 120 gave their written consent to participate in the study and attended an information session. Two medical practices did not meet the inclusion criteria, and 3 GPs refused to participate due to time limitations. Of the remaining 115 practices 75 were randomly selected, stratified into rural or urban, and randomly assigned to either the control group or 1 of the 2 intervention groups (figure 1). Analysis of variation of cluster sizes revealed that the number of patients varied between 11 and 15 at baseline. No practice dropped out during the study (the chart displays the loss of patients). Of the 1,311 patients invited to participate by the GPs, 1,125 agreed to complete the set of questionnaires and 1,021 sets

were returned to the university at baseline; in 795 (77.9%) cases, questionnaires were returned post-intervention.

Missing data occurred mainly within the same questionnaire, and in most cases the data could be completed from the patient file. An initial comparison of the 1,021 respondents and the nonrespondents revealed no significant differences with respect to sociodemographic variables (age, sex), disease characteristics (duration of disease), or number of comorbidities and prescribed medication. A total of 674 (66.0%) of the included patients were women with a mean ± SD age of 66.6 ± 15.3 years, whereas men had a mean ± SD age of 65.2 ± 14.8 years.

The baseline characteristics of the study sample, separated for the control group and the two intervention groups, are displayed in table 1. Group comparison revealed no significant differences between the control group versus intervention group I and intervention group II.

Table 1. Characteristics of the study sample (n = 1,021) at baseline*

Characteristic	Control group (n = 25)	Intervention group I (n = 25)	Intervention group II (n = 25)
General practitioners			
Number	25	25	25
Working experience, mean ± SD years	23.1 ±18.2	22.2 ± 19.1	21.9 ± 18.7
Location (rural/urban)	14/11	13/12	14/11
Patients			
Number	332	345	344
Female sex	229 (68.9)	214 (62.0)	231 (67.2)
Age, mean S±D years	66.11 ± 15.02	65.59 ± 14.68	66.27 ± 15.19
Education level, mean ± SD	2.59 ± 1.07	2.45 ± 1.13	2.48 ± 1.02
Living in partnership	225 (66.3)	203 (58.8)	226 (65.7)
Retired	219 (65.7)	241 (69.9)	255 (74.1)
Kellgren score, mean ± SD	2.56 ± 0.87	2.71 ± 0.92	2.59 ± 0.79
Duration of OA, mean ±SD years	13.3 ± 14.1	13.9 ±13.0	13.4 ± 14.2
PHQ-9 score, mean ±SD	15.2 ± 4.8	15.1 ± 4.9	15.4 ± 5.2
Comorbidities			
High blood pressure	187 (56.3)	195 (56.5)	182 (53.8)
Chronic heart failure	58 (17.5)	70 (20.3)	61 (17.7)
Coronary vessel disease	45 (13.6)	38 (11.0)	41 (11.9)
Diabetes	63 (19.0)	58 (16.8)	55 (16.0)
Cholesterol	126 (38.0)	136 (39.4)	140 (40.7)
COPD/asthma	37 (11.1)	36 (10.4)	35 (10.2)

* Values are the number (percentage) unless otherwise indicated. OA = osteoarthritis; PHQ-9 = Patient Health Questionnaire; COPD = chronic obstructive pulmonary disease.

The primary and secondary outcome measures at baseline are displayed in table 2. QoL was reflected in 5 different AIMS2-SF dimensions, but because most of the participants were already retired we excluded the work scale from further analysis, because this dimension is only applicable if the patient is not retired. Regarding

prescriptions, total numbers and percentages of patients receiving at least 1 DDD of the specific drug are mentioned. Group comparisons revealed no statistically significant differences in the outcome measures.

Table 2. Primary and secondary outcome measures at baseline*

	Control group (n=332)	Intervention group I (n=345)	Intervention group II (n=344)
Primary outcome			
Quality of life (AIMS2-SF scores)			
Lower body	2.65 ± 1.85	2.67 ±1.88	3.01 ± 2.11
Upper body	1.33 ± 2.09	1.47 ±2.25	1.68 ± 2.44
Symptom	4.81 ± 2.18	4.87± 2.13	5.02 ± 2.29
Affect	2.88 ± 1.33	2.89 ±1.35	3.04 ±1.39
Social	4.69 ± 1.80	4.52 ± 1.88	4.79 ±1.80
Secondary outcomes			
Health service utilisation			
GP contacts	4.82 ± 6.00	4.56 ± 6.13	5.01 ± 5.78
Referrals to orthopedics	1.76 ±3.52	1.58 ± 3.43	1.76 ± 3.52
Radiographs	0.79 ± 2.78	0.82 ± 3.12	0.80 ± 3.01
Nonmedical practitioner	0.36 ±3.28	0.11 ± 3.01	0.50 ±4.20
Physiotherapy	5.81 ±11.10	4.70 ± 9.10	5.22 ±10.03
Acupuncture	0.97 ± 3.80	0.83 ± 3.45	0.77 ± 3.99
Physical activity/BMI			
IPAQ total score (MET, minutes/week)	2,356.2 ± 1,982.5	2,209.7 ± 1,979.2	2,401.1 ± 1,992.3
BMI, kg/m2	28.39 ± 5.09	28.02 ± 4.45	28.12 ± 4.57
Prescriptions, no. (%)†			
Acetaminophen	22 (6.6)	31 (8.9)	25 (7.3)
Opioids	23 (6.9)	20 (5.8)	25 (7.3)
NSAID	139 (41.9)	138 (40.0)	149 (43.3)
Homeopathics	27 (8.1)	21 (6.1)	23 (6.7)

* Values are the mean ± SD unless otherwise indicated.
AIMS2-SF = Arthritis Impact Measurement Scales Short Form; GP = general practitioner; BMI = body mass index; IPAQ = International Physical Activity Questionnaire; MET = metabolic equivalent; NSAID = nonsteroidal antiinflammatory drug. † Numbers of patients receiving a defined daily dose.

The results of the intervention are displayed in table 3 as differences in mean scores between pre- and post-intervention for each group. The provided P values resulted from comparison of changes in means between the control group and the respective intervention group. The analyses using ANCOVA were controlled for the covariates age, disease duration, ICC and PHQ-9 score. As can be seen, changes in means did not differ between intervention group I and the control group with respect to the primary outcome. Significant results in intervention group I only occurred in the secondary outcome parameters: radiographs (P=0.050) and percentage of prescriptions of acetaminophen (P < 0.001). In intervention group II, significant increases in QoL were revealed in the symptom scale (P=0.048), reflecting patients' perceived pain; the lower limb scale (P=0.049), assessing patients' functional ability in the lower limbs; and the social scale (P < 0.001).

Table 3. Mean changes in outcome measures between baseline and post-intervention assessment in the control and intervention groups*

	Control Group (n = 258)	Group I (n=261)	ANCOVA P (group I vs. control)†	Group II (n=276)	ANCOVA P (group II vs. control)†
Primary outcome					
Quality of life (AIMS2-SF scores)					
Lower body	0.03 (-0.21, 0.24)	0.19 (-0.01, 0.38)	0.349	0.40 (0.16, 0.64)	0.049
Upper body	-0.01 (-0.29, 0.28)	0.04 (-0.25, 0.29)	0.694	0.06 (_0.20, 0.27)	0.621
Symptom	0.09 (-0.09, 0.20)	0.36(0.19, 0.56)	0.119	0.60 (0.28, 0.92)	0.048
Affect	0.05 (-0.12, 0.18)	-0.03 (-0.17, 0.11)	0.610	0.06 (_0.13, 0.20)	0.691
Social	0.07 (-0.05, 0.19)	0.09 (-0.02, 0.20)	0.776	0.54 (0.44, 0.86)	< 0.001
Secondary outcomes					
Health service utilisation					
GP contacts	0.22 (-0.21, 0.45)	0.12 (-0.24, 0.36)	0.339	0.11 (_0.23, 0.34)	0.823
Referrals to orthopedics	0.01 (-0.05, 0.06)	0.09 (0.02, 0.15)	0.153	0.24 (_0.16, 0.31)	0.044
Radiographs	-0.06 (-0.13, 0.01)	0.07 (-0.01, 0.15)	0.050	0.09 (0.02, 0.16)	0.031
Nonmedical practitioners	0.04 (-0.02, 0.11)	0.02 (-0.06, 0.08)	0.687	0.03 (_0.06, 0.09)	0.225
Physiotherapy	0.04 (-0.05, 0.12)	0.07 (-0.04, 0.18)	0.242	0.14 (0.02, 0.23)	0.129
Acupuncture	-0.12 (-0.23, 0.02)	0.03 (_-.22, 0.25)	0.821	0.05 (_0.18, 0.27)	0.769
Physical activity/BMI					
IPAQ score	125.2 (103.8, 146.6)	131.5 (104.3, 157.2)	0.778	133.4 (118.6, 148.2)	0.667
BMI (kg/m2)	0.09 (-0.06, 0.24)	-0.13 (-0.16, 0.03)	0.224	_0.14 (_0.17, 0.03)	0.134
Prescriptions, %‡					
Paracetamol	-1.31 (-3.01, 0.39)	7.43 (3.33, 11.53)	< 0.001	6.89 (2.93, 10.70)	< 0.001
Opioids	0.98 (-1.32, 3.28)	4.33 (3.32, 5.34)	0.077	8.80 (5.02, 12.58)	< 0.001
NSAID	2.31 (0.91, 3.71)	4.30 (2.82, 5.78)	0.076	6.54 (4.54, 8.54)	0.019
Homeopathics	1.71 (-0.49, 3.91)	1.58 (-0.52, 3.68)	0.168	2.94 (0.64, 5.24)	0.088

* Values are the mean change (95% confidence interval) unless otherwise indicated. ANCOVA = analysis of covariance; see Table 2 for additional definitions.

† ANCOVAs were adjusted for age, disease duration, PHQ-9 score, and intracluster correlation coefficient.

‡ Percentage of patients receiving a defined daily dose of the specified drug

As in intervention group I, significant changes also occurred with respect to health service utilisation: orthopaedic referrals (P=0.044) and radiographs (P=0.031) decreased significantly. Prescriptions of acetaminophen (P < 0.001), nonsteroidal antiinflammatory drugs (P=0.019), and opioids (P < 0.001) changed significantly. Referrals to nonmedical practitioners and physiotherapists showed no notable changes. Interestingly, the IPAQ score increased in all 3 groups, but differences between groups were not significant.

Discussion

Multifaceted educational interventions with GPs provided through quality circles had no impact on patients' QoL or physical activity. However, the interventions seemed to reduce certain aspects of health service utilisation such as radiographs, and to change prescription patterns. Additional case management by practice nurses involving a frequent, structured follow-up with immediate feedback to GPs was able to increase certain dimensions of QoL such as pain and social contacts in patients with OA.

Although it is of great importance; providing arthritis self-management in primary care seems to be a big challenge. Buszewizc et al. provided ASMPs directly to a large sample of primary care patients and achieved no significant changes in pain and physical functioning after 4 and 12 months.[7] Contrary to that study our intervention primarily focused on the GP, but the results of our intervention group I suggest that an approach that mainly uses educational interventions through GPs, even if the interventions are accompanied by written material and patient information leaflets, has no effect on patients' QoL. We were not able to evaluate how much of the information provided to the GPs finally reached the patient, but our results fit quite well with previous findings regarding the impact of educational interventions. Bloom reported that the impact of educational interventions on patients through GPs is low[34]. Regarding the effect of case management, some impressive effects have already occurred in other contexts. Simple routine telephone calls were found to positively influence physical functioning and pain in patients with OA[35] and QoL of patients with diabetes[36]. Our intervention was more complex than a simple telephone call, and our results indicate that case management including a structured, disease-specific monitoring tool can have the same or even superior effects. Positive effects from case management have also been shown for depression[12], but previous studies have revealed inconsistent results for other diseases. It seems that the complexity of case management is correlated with the results[37]. However, Moher et al.[38] noticed that just setting up a

patient register improved the planned follow-up of patients. Nevertheless, it remains unclear to what extent the effect in intervention group II, especially regarding the social scale, is due to the telephone calls, or due to frequent follow-ups.

Regarding health service utilisation, in both intervention groups the number of radiographs were reduced significantly, and in intervention group II so were referrals to orthopaedics. This finding indicates that educational interventions may be appropriate to achieve effects on the GP level, in the form of referral rates. But it should be acknowledged that referral rates to nonsurgical orthopaedics, as well as the number of radiographs, are extremely high in Germany[18]. This may have helped to achieve a significant reduction in referrals. It should also be mentioned that there have been studies in which outcomes such as guideline adherence were improved using a largely educational intervention through GPs[39].

With respect to the effects on prescription, it has to be acknowledged that the prescriptions of acetaminophen, the first-line treatment of OA according to most guidelines, and the proportion of patients receiving opioids were low at baseline. Therefore, significant changes were easy to achieve. Nevertheless, our findings confirm that peer group meetings can be useful instruments in changing prescription patterns[11]. Interestingly, Moher et al. recently demonstrated that a structured follow-up of patients with coronary heart disease is more effective if performed by practice nurses than by GPs[38]. Regarding adherence to prescriptions, a recent study demonstrated that frequent telephone calls can increase patients' compliance significantly and even reduce mortality[40].

An interesting finding was that physical activity increased in all three groups with no significant changes between the groups. We assume that this occurred because the baseline assessment took place in early spring, and the post-assessment took place 9 months later at a time when the weather is warmer and more compatible with outdoor activities. The possible effect of counseling provided by GPs seems to be weak, as a recent meta-analysis has indicated[41]. However, Elley et al.[42] who implemented counseling for physical activity by telephone calls demonstrated that this intervention increased physical activity in patients; a finding that was confirmed by Castro and King[43].

Some limitations of the revealed effect should be acknowledged. First, the number of patients required to achieve the initially assumed power of 90% was not reached, but it should be noted that the number would have been adequate for a power of 80%. Regarding the validity of the data, some data such as consulting nonmedical practitioners could not be infallibly recorded on the medical file.

Moreover, information about prescriptions and referrals was only available if initiated by the GP. Besides the large sample size of primary care patients, the study has additional strengths: 1) we used a disease-specific assessment instrument for QOL that may be more sensitive to patient-relevant changes; 2) to our knowledge, this is the first study to assess case management in patients with OA and 3) we controlled our data for severity of depression, the prevalence of which is known to be increased in patients with OA[21]. Depression has a detrimental effect on certain important dimensions of QoL such as pain and physical ability. Regarding the generalisability of our results, the 75 GPs most likely reflect a representative sample in terms of localisation, working experience, practice size and nursing support.

Providing arthritis management seems challenging, and educational interventions on the GP level, even if multifaceted, do not appear to achieve significant effects on QoL. Additional case management by practice nurses increases the effect and improves certain dimensions of patients' QoL significantly. Our results encourage further research using similar approaches in other chronic diseases.

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General discussion

Introduction

Although the figures regarding the prevalence of radiological or symptomatic osteoarthritis (OA) vary, there is no doubt that OA is highly prevalent and that primary care has an outstanding role in the diagnosing process and treatment of OA. In contrast to that, astonishingly little research on OA patients in primary care is available. In the first section of this thesis we presented several studies on the quality of life of OA patients, their needs and perspectives. We also presented the German validation of one the most widespread instrument to assess QoL, the Arthritis Impact Measurement Scale (AIMS), and showed that GPs assessment of patients' QoL is dominated by pathological changes.

In the second section we highlighted the implications of depression for the QoL of OA patients and the impact on their health service utilisation (HSU). Furthermore, the impact of obesity on QoL and the determinants of pain, one of the strongest predictors of QoL, were assessed.

In the third and final section quality and outcomes of current primary care were examined, and ideas for larger involvement of the practice nurse were explored. And finally we tested the impact of case-management provided by practice nurses in a large cluster-randomised trial.

Discussion of the main findings

Quality of life

Prior research had shown that pain and disability were the major burdens of OA[1-4], and that patients with OA desire more information[5]. This was also reflected in the results of our qualitative study, presented in chapter one. Our results helped to specify the content of information for patients: patients are mainly interested in the impact of OA on their individual situation regarding pain and mobility rather than on information about the pathology of the disease. Interestingly, a similar result was revealed by Grime et al. regarding patient information leaflets for OA[6]. Considering this, it might not surprise that many patients felt their main fear, the individual course of the disease, to be insufficiently addressed. A similar lack in communication could be revealed regarding pain treatment and advice for lifestyle changes: GPs should emphasise the meaning of physical activity with individual advice. They should also emphasise that pain medication should be used to enable daily physical activity and not be used as a "rescue" treatment.

In research QoL has become an important parameter and outcome measure; for instance in evaluations of treatments. A wide range of instruments has been

developed to assess patients' QoL. Studies have shown that disease specific instruments are often more appropriate than generic ones. Regarding OA, there are three instruments which are of importance: The Western Ontario and Mc Master Universities Index (WOMAC)[7], the Lequesne - Index [8] and the AIMS2, of which a revised short and long version are available.[9;10] As in many chronic diseases, the impact of OA on QoL interferes with many individual factors as e.g. psychological and social ones.[11-14] The advantage of the AIMS is that it is more comprehensive then the WOMAC and the Lequesne-Index and can be used without further instruments as e.g. the SF-36, even if a complex overview of all dimensions of QoL is of interest. We validated both versions of the AIMS2 in two different groups of patients. The psychometric properties of both versions were convincing, and in conclusion we showed with our study that both versions of the AIMS2 are reliable and valid instruments. The acceptance in a primary care setting was high, as reflected in the high response rate and the low amount of missing values, so that these two instruments are now available for the assessment of QoL in research as well as practice in primary care.

Our qualitative study, presented in chapter one, showed that physicians have a very pathomorphological approach to OA and focus on "visible" affections of OA on the joints. Based on these qualitative finding, and with the validated AIMS2, it seemed interesting to reveal the determinants of physicians' perceived QoL of patients with OA. Therefore, we compared a global physician assessment of patients' QoL with the AIMS2-SF, the WOMAC and X-rays. In conclusion, and in accordance with our qualitative results, the study suggested that physicians' assessment of patients' QoL is mainly dominated by physical factors, namely pain and severity of X-ray findings. Socioeconomic and psychosocial factors, which are known to have a substantial impact on QoL, were underestimated or missed. This finding is in accordance with previous findings showing, for instance, that depression or depressive symptoms are often missed.[15] Moreover, the overestimation of X-ray findings, which are known to be less correlated to QoL, may cause over-treatment, while important and promising targets to increase patients' QoL are missed [16;17].

The main predictors for QoL of OA patients are pain and functional disability. Many studies have shown the substantial impact of pain on quality of life[18;19] and on health service utilisation (HSU)[20], especially among OA patients. Even the association between depression and pain has been investigated for a long time; research in large primary care patient groups was not yet available.[21-24] Our results

showed that severity of depression reflected in the Patient Health Questionnaire (PHQ)-9 score is the strongest predictor for pain intensity in OA patients. These results are in line with previous findings from smaller samples, or samples from hospital settings.[18;19] Some prior studies also indicated that psychosocial aspects are important for pain perception; a result which could be confirmed in our large sample of primary care patients. Furthermore, we could show the close association between the educational level and pain perception as well as the contribution of the social network to the burden of OA.[26] As mentioned above, functional disability is also of great influence on the QoL of OA patients. Our studies emphasised the strong association of depression and functional disability and confirmed prior findings, assessing less covariates and/or focusing on smaller patient groups.[1;3;25]

Taking into account that psychosocial aspects are often not recognised appropriately, our results emphasise again the importance of awareness for depression and psychosocial factors, especially in patients with chronic diseases.[15] The GP is the physician who is more familiar with the social background than any other physician, and so he is predestined to consider this important factor in pain treatment.

Comorbidities and health service utilisation

We found that, as in many other chronic diseases, an increased prevalence of depression among OA patients[27-31] (chapter 5). But depression did not only have a substantial impact on individuals' QoL, it resulted also in increased use of the health care system[32]. This finding had been found in patients with depression before, but not that it also results in increased use of medical professions which are involved in the care of OA patients. On the other hand, contacts with providers of Complementary Alternative Medicine (CAM) offered e.g. by "healers" were not significantly increased. In conclusion, and continuing our findings presented in the first section, the challenge in daily care obviously is to be aware of concomitant depression in OA patients and to treat the whole patient, not only the affected joint. Our results suggest that this will not only increase patients' QoL but also reduce inappropriate consultations and procedures.

Body weight, the body mass index (BMI) respectively, is the strongest modifiable risk factor for OA. This was the finding of many large studies, including the Framingham population.[33;34] But even if OA is already symptomatic, reducing body weight leads to less pain and less functional disability as a recent review pointed out.[6] So far and similar to depression, only few data existed about the association

of obesity with quality of life, health service utilisation and physical activity within the same sample of OA patients. Our results, which assessed the impact of obesity on QoL are in accordance with prior studies and showed that obese and overweight persons achieved significantly higher scores on the AIMS2-SF lower body scale, the symptom, the affect and the work scale, indicating an increased burden by OA.[35] Prevalence of depression, highlighted already several times in this discussion, increased significantly over the three weight-groups and confirmed the result of prior research, indicating an association of body weight and depression[36]. Also in accordance with findings within other diseases, with increasing BMI, the number of comorbidities -especially cardiovascular ones – also increased as the physical activity decreased significantly. As many studies – focusing on diabetes or cardiovascular diseases, our results emphasised the need for appropriate approaches in primary care to break the vicious circle of overweight, depression, decreasing physical inactivity and decreasing QoL from the perspective of OA patients.

Improving the quality of care

The research presented in chapter 10 and 11 focused on the delivery of care. In chapter 10, we analysed to what extent current care for OA patients was consistent with the Chronic Care Model (CCM), which claims to reflect the core elements of patient-centred care in chronic diseases[37;38]. In comparison to data available from Health Maintenance Organisation (HMO) settings in the United States (US), our data indicated that the core elements of chronic care were less present in German primary care, a finding which has recently also been found in German diabetes patients[39-41]. Furthermore, the data showed that younger and better educated patients achieved higher scores on the PACIC score, indicating that their care accords to a higher degree with the CCM. Whether this reflects differences in physician behaviour toward different patient groups or rather different demands of these patient groups cannot be concluded from the presented data. Further research is needed to confirm our results and to reveal possible limitations of the CCM since it may be only appropriate for certain patient groups.

Regarding OA patients, satisfaction with healthcare delivery has been assessed regarding certain types of treatment such as pain treatment or surgical interventions[42;43]. Our hypothesis was that, similar to the results regarding these

treatments, disease specific quality of life will have a substantial impact on patient evaluation of care provided. But interestingly, beside the duration of OA, no disease related factor was associated with patient evaluations of care. Our results indicate that psychosocial factors are more important to explain the care provided than disease-related aspects. This finding emphasises the awareness of these factors from a completely different point of view.

Many approaches to enhance care for chronically ills, as for instance the CCM model, require a team approach and the involvement of, for instance, practice nurses[44-46]. And indeed, there is good evidence that involvement of nurses in primary care can improve specific aspects of healthcare[47;48]. Since positive effects of nurse involvement have neither been shown in large samples of primary care patients with OA, nor in the German health care system it was our aim to assess such an approach in a large cluster-randomised controlled trial (RCT). The German health care system is physician-centred and it was completely unclear if and to what extent practice nurses could be involved in the care for chronically ill patients. In detail it was unclear what practice nurses themselves, but also general practitioners (GPs) and patients think about such a team approach. Our qualitative study (chapter 11) showed that practice nurses were only marginally involved in the treatment of patients, especially in OA. One important obstacle, mentioned by GPs, practice nurses and patients, was the lack of nurses' medical knowledge. There was a consensus that current education for practice nurses obviously provides only a rudimentary professional medical background. Beside that point, most patients were optimistic regarding the involvement of nurses. Only few patients feared a worsening of the patient-doctor relationship. In conclusion, our study showed that the German health care system is far away from providing resources for a real team approach as provided in many other health care systems where established professions such as physician assistants exist[48]. The changes that need to be made are mostly on a political level and out of the reach of individual physicians.

The implications of that finding for our RCT were quite obvious: The involvement had to be reduced to a simple but structured monitoring of the patients with a specially developed tool, the "Arthrosis Monitoring List" (ArtMoL). Bloom et al. pointed out in a review of interventions which are appropriate to result in significant changes that the effect of simple educational interventions is low[49]. Our results confirmed that result, since in the group which just received education no significant changes in QoL could be recognised. In the group which performed an additional case management, which consisted of frequent telephone calls based

on the ArthMoL, we could achieve significant changes in some areas of the disease specific QoL. Telephone calls, even if not accompanied by a structured monitoring tool, have shown to be an effective procedure in completely different settings: they increased physical activity, reduced pain and even mortality[50-52]. Our results suggest that they are very effective if combined with a structured tool such as the ArtMoL. Based on our results, structured telephone tools are currently used in further projects as for instance in patients with heart insufficiency or depression[53;54]. So, hopefully further results to confirm our findings will come forth, thus enabling advances in the tool and consequently in the care for chronically ills.

Methodological considerations

Limitations of the qualitative research

Our qualitative studies had the limitations that are inevitably associated with this type of research: the statements reflect individual opinions, and self reported behaviour may not adequately reflect the real behaviour or does not reflect reality. For instance, if GPs report they have no problem in distinguishing articular from periarticular pain this does not mean that they are correct in doing so. Another limitation is that the results are appropriate for the German health care system and cannot easily be transferred to other health care systems.

Limitations of the quantitative research

The analysis based on the PraxArt- population of OA patients in primary care had a number of limitations. First of all, some of the data such as, e.g, the data about contacts with providers of complementary alternative medicine, or the over-the-counter- (OTC) medication were based solely on patients' replies. Contrary to most other data they could not be checked by means of the patient file. Regarding the RCT, the required number of patients to achieve the initially desired statistical power of 90% was not reached, but it should be noted that it was adequate for a power of 80%. Furthermore, it has to be noted that we tested the intervention against a control group with no intervention at all (except usual primary care). To assess the efficacy of case management, that it is “pure effectiveness”, it should have been tested against a “placebo-intervention” (e.g. simple telephone calls involving only conversation but no medical content). Furthermore, it remains unclear if a more complex approach - as required for care according to the CCM - can be implemented in primary care in Germany. The evaluation of complex interventions, such as the Chronic Care Model, remains a scientific challenge.

Strengths of the study

On the other hand, the studies presented in the thesis had a number of strengths: we had a large sample size of primary care patients and we used a disease-specific and validated measure on QoL. Furthermore, to our knowledge this thesis presented the first study to assess case management in OA patients. As initially assumed and displayed in chapter 5, depression is an important comorbidity and of great influence on QoL but also for health service utilisation. Depression has also a detrimental effect on physical ability. Consequently, we controlled our analysis of the RCT for this covariate. Regarding the generalisability of our results, the 75 GPs most likely reflect a representative sample in terms of localisation, working experience, practice size and nursing support.

Implications for practice and future research

Our results confirmed in large primary care setting what has been found in hospital settings before: Psychosocial factors contribute tremendously to the quality of life of OA patients and are also important predictors for the use of the health care. And interestingly, even the GP who is more familiar with the psychosocial background of the patient as any other physician had a very pathomorhoplogical and mechanical idea of the QoL of OA patients (at least in Germany). As a consequence, psychosocial aspects were often not assessed, underestimated and not targeted in the treatment. GPs tried to distinguish between “somatic” and “psychological” problems instead of understanding them as closely related and influencing them reciprocal. These findings imply for daily practice, that physicians should always focus on the individual’s perspectives and QoL rather than on providing pathophysiological explanations which are not appropriate to decrease patients’ fears. Individuals’ QoL and not only actual pain and functioning have to be the targeted. Further research is needed to assess how GPs’ awareness for these factors could be increased, and also what type of treatments or counselling by the GP could effectively influence these factors. Possible approaches could assess, for instance, the use of structured screening tools for pain and depression as the PHQ-9, the AIMS2-SF or just a simple visual analogue scale (VAS). Furthermore, methods are needed to influence risk factors for OA, for instance, effective counselling to increase physical exercise. But without a doubt, appropriate consultation time is also an important condition to assess patients’ QoL and influence their behaviour. Politicians should be aware that the current trend to increase administrative workload and to pay physicians for the amount of

contacts rather than the time spent with the patients contradicts the needs of chronically ill patients.

Proactive and structured care requires the involvement of practice nurses. GPs should abandon their fears and be more open minded towards team approaches. It seems inconsistent that to complain about an increasing workload on the one hand and at the same time to defeat the distribution of the work on more shoulders. As our large cluster-RCT suggested - similar to some studies before - involvement of non-physician practitioners increases the quality of care and also patients QoL. And in the long run it may also decrease the workload for the physician, although current research evidence is not conclusive on this. Obviously, such involvement of nurses requires professional development of the nurses themselves – e.g. special training programmes to qualify for working in primary care settings. But as prior studies indicated, politicians should also abandon the idea that this will decrease costs. How more complex approaches, such as the involvement of practice nurses, could be implemented in the physician-centred German health care system has to be the subject of future research.

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Summary

Chapter 1

Chapter 1 reports the results of a qualitative approach on the views of patients, general practitioners and practice nurses on the current situation of care for OA patients in general practice in Germany. The main findings were that diagnosing OA represents no challenge for GPs. But in assessing pain and physical disability the GPs often found it difficult to distinguish between complaints resulting from the affection of the joints and complaints related to a concomitant depression. Patients felt to be well-informed about the degenerative nature of the disease and possible side effects of medications, but they lacked information on individual consequences of the disease. Therefore, the most important concerns of many patients were pain and fear of disability which they felt to be addressed by GPs only marginally. Regarding pain treatment, physicians and patients had an ambivalent attitude towards non-steroidal anti-inflammatory drugs (NSAIDs) and opiates. Therefore, pain treatment was not performed according to prevailing guidelines. GPs felt frustrated about the impact of counselling regarding lifestyle changes, but on the other hand admitted to have no systematic approach to it. Patients stated to be aware of the impact of lifestyle on OA but lacked detailed information, e.g., on how to exercise. Several suggestions were made concerning improvement.

Chapter 2

To assess quality of life, valid and reliable instruments are required. In chapter 2 the process of translation and validation of the most widespread instrument to assess QoL of OA patients, the Arthritis Impact Measurement Scale 2 (AIMS 2) and its short form the AIMS 2-SF, are given. Both instruments were translated into German and culturally adapted. Each of the questionnaires was then administered to 220 primary care patients with OA of the knee or hip. 209 (long version), questionnaires were returned and analysed. Test-retest reliability was tested in 50 (long version), respectively 35 (short form) randomly selected patients. The “physical” scale of the original AIMS2-SF was divided into an “upper body limitations” and a “lower body limitations” scale. In both versions the assessment of internal consistency reliability revealed satisfactory values; Cronbach's alpha was 0.77 or higher for all scales of the long version and 0.83 or higher for all scales, except for the “social interaction” scale (0.66 of the short version). The test-retest-reliability, estimated in an intraclass-correlation-coefficient (ICC), exceeded 0.90, except the “social activities” scale (0.87) in the long version. In the short version the ICC exceeded 0.85, except the “affect” scale (0.72). Since only

patients with OA to the lower limb were enrolled, substantial floor effects occurred in the “arm function” (28.2 %) and the “hand and finger function” scale (29.2) in the long version and in the “upper limb scale” (33.8 %) of the short form. The principal factor analysis confirmed the postulated three-factor structure with a physical, physiological and social dimension for both versions. External validity was assessed by calculating correlations to the Western Ontario and Mc Master Osteoarthritis Questionnaire (WOMAC): a visual analogue scale for pain (pain-VAS) and radiological severity of joint affection (assessed by means of the Kellgren and Lawrence score). Spearman’s “R” achieved satisfactory values for the corresponding WOMAC scales and the pain-VAS. Correlations with the radiological grading were low. In conclusion, our validation studies showed that both versions of the AIMS2 are reliable and valid instruments to assess the quality of life in primary care patients suffering from OA. While addressing different impacts of OA the physical scale should be divided in an “upper body” and “lower body” scale. The revealed floor and ceiling effects are in accordance with the disease characteristics of the study sample and do not limit the significance of the questionnaire.

Chapter 3

The aim of chapter 3 was to assess determinants of physicians’ estimation of patients’ QoL. Therefore, we included 220 primary care patients with OA of the knee or the hip treated by their general practitioner for at least one year. All GPs were asked to assess patients’ QoL based on the patients’ history, actual examination and existing X-rays by means of a visual analogue scale (VAS scale), resulting in values ranging from 0 to 10. Patients were asked to complete the McMaster Universities Osteoarthritis Index (WOMAC) and the Arthritis Impact Measurement Scale2 Short Form (AIMS2-SF) questionnaire. The results showed significant correlations between the GP assessment and the AIMS2-SF scales “physical” and “symptom” as well as to the “pain” scale of the WOMAC. A multivariate ordinal regression analysis revealed only the AIMS2-SF “symptom” scale and the X-ray grading according to Kellgren and Lawrence as significant influences of the GPs’ assessment of QoL. In conclusion, the results of our study suggested that physicians’ assessment of patients’ QoL is mainly dominated by physical factors, namely pain and severity of X-ray findings. The results also suggest that socioeconomic and psychosocial factors, which are known to have substantial impact on QoL, are underestimated or missed.

Chapter 4

The aim of chapter 4 was to assess predictors of depression in a large sample of primary care patients with osteoarthritis. Patients were approached consecutively in 75 general practices. Of 1,250 distributed questionnaires, 1,021 were returned and analysed. Besides sociodemographic data, medication and comorbidities, depression and arthritis were assessed using the Patient Health Questionnaire (PHQ-9) and the Arthritis Impact Measurement Scale (AIMS2-SF). A stepwise multiple linear regression analysis with the PHQ-9-score as the dependent variable was performed. According to the PHQ-9, 19.8 % of men and 19.2% of women achieved a score of 15 or higher, indicating at least a moderately severe depression. Interestingly, significant gender differences could not be revealed. The strongest predictor for depression severity was perceived pain and few social contacts. Further predictors were physical limitation of the lower body as well as of the upper body, age and the body mass index. The findings suggest an increased prevalence of depression among OA patients and emphasise the need for recognition and appropriate treatment. Most of the revealed predictors are influenceable and should be potential targets in a comprehensive treatment of OA in order to interrupt the vicious circle of pain, physical limitation and depression.

Chapter 5

The aim of the paper in chapter 5 was to assess the impact of concomitant depression on quality of life and health service utilisation in patients with osteoarthritis. Data from 1,021 outpatients from 75 general practices enrolled in the PraxArt project were analysed. Measures included sociodemographic data, a short form of the Patient Health Questionnaire (PHQ-9) to assess depression. Data about health service utilisation (contacts with GPs, orthopaedics and to providers of complementary alternative medicine) were retrieved by straight forward questions as well as by means of patients' medical. The results showed that patients with a depressive disorder showed significantly more frequent contacts with GPs ($p<0.01$), orthopaedics ($p<0.01$) but not with providers of complementary alternative medicine offered, e.g., by healers. The findings provided a more differentiated view on health service utilisation patterns. It could be concluded that depressed patients tend to visit providers where they can remain passive.

Chapter 6

The aim of the study presented in chapter 6 was to assess the association of obesity with quality of life, health service utilisation and physical activity in a large sample of primary care patients with osteoarthritis (OA). In 978 patients from the PraxArt project, height and weight were measured and the body mass index (BMI) was calculated. The AIMS2-SF was used to assess quality of life (QoL). Data on health service utilisation (HSU) were retrieved by means of patients' medical files. Concomitant depression was assessed by means of the Patient Health Questionnaire (PHQ-9). Patients were grouped into normal weight, overweight and obese according to the definition of the WHO and compared by means of analysis of covariance (ANCOVA). Obese and overweight persons achieved significantly higher scores on the AIMS2-SF lower body scale, the symptom, the affect and the work scale, indicating an increased burden of OA. The PHQ-9 score increased significantly over the three weight-groups, indicating a positive association of BMI and depression. With increasing BMI, the number of comorbidities increased and physical activity decreased significantly. After controlling for covariates, contacts with orthopaedics and performed X-rays remained significantly higher in obese patients but not contacts with general practitioners.

Chapter 7

Pain represents one of the most important predictors of quality of life in patients with osteoarthritis. But most studies assessing pain failed to control important covariates such as depression, obesity or physical activity. Therefore, we aimed to determine factors associated with pain intensity in a large sample of OA patients in primary care. In a regression model with the "symptom" dimension of the AIMS2-SF as dependent four factors remained explaining 47.9 % of the variation: severity of depression reflected in the PHQ-9 score influences pain intensity the most (beta = 0.459, $p<0.001$). Functional disability of the lower limb accounted for a beta of 0.427 ($p=0.003$). A low educational level was associated with increased pain scores (beta=-0.321; $p=0.029$) as was disease duration (beta=0.178; $p= 0.017$). The social contacts/network, addressed by the AIMS social scale accounted for a beta of 0.211 ($p=0.040$). Our study showed that a variety of physical and psychological factors was associated with pain intensity.

Chapter 8

Patient satisfaction is an important indicator for the quality of care provided to OA patients. Previous studies focused on patient satisfaction regarding certain

treatments such as, e.g., surgical interventions or pain treatment. The aim of the study presented in chapter 8 was to assess current satisfaction of OA patients and to assess if disease related factors are important for satisfaction. Within the sample of 1,021 OA patients, QoL was assessed by means of the AIMS2-SF and patient satisfaction was measured by means of the EUROPEP instrument. A stepwise linear regression analysis with the EUROPEP score as dependent variable controlled for the amount of GP visits was performed to assess predictors of satisfaction. Contrary to our assumptions, only the duration of OA (beta=-0.105; p=0.008) and no other disease related factor was associated with patient satisfaction. The main predictors were the depression score (beta=-0.372; p<0.001), age (beta=-0.185; p<0.001), living alone (beta=-0.209; p<0.001), number of comorbidities (beta=-0.152; p<0.001).

Chapter 9

The aim of chapter 9 was to assess to what extent current care for patients with osteoarthritis accords with the Chronic Care Model in Germany. In addition, we tried to reveal possible predictors of a high congruency and to assess the question whether certain patients are more likely to receive care complying with the CCM.
The Patient Assessment of Chronic Illness Care (PACIC-5A) was used to assess accordance to the CCM, QoL was assessed by means of the Arthritis Impact Measurement Scale (AIMS2-SF). The PACIC sum score was notably lower than in previous studies conducted in HMO settings in the US. The stepwise multiple linear regression models, with the PACIC sum score and the 5A score as dependents, revealed that the PACIC score was associated with a higher educational level (beta= 0.421; p=0.008) and younger age (beta=-0.319; p=0.016). The 5A score was predicted by educational level (beta=0.344; p=0.002), age (beta=- 0.386; p=0.004) and the PHQ-9 score (beta=- 0.288; p=0.005). In conclusion, our results showed that younger and better educated patients achieve higher scores on the PACIC score. Why these patients received care that complies to the CCM more remains unclear.

Chapter 10

In chapter 10 we aimed to reveal possibilities to involve the practice nurse in the care of osteoarthritis patients. We performed qualitative, semi-structured interviews with 20 GPs, 20 practice nurses and 20 patients in the Heidelberg area. The interviews were digitally recorded, transcribed and content-analysed with Atlas.ti. Our results showed that practice nurses are only marginally involved in the

treatment of patients with OA. GPs as well as patients are very sceptical about their increased involvement in care. Patients were sceptical about nurses' professional background and feared a worsening of the patient-doctor relationship. GPs also complained about the nurses' deficient education concerning medical knowledge. They feared a lack of time as well as lacking reimbursement for the efforts of an increased involvement. Practice nurses were mostly willing to be more involved; regarding it as an appreciation of their role. The most important barriers we revealed were lack of time, overload with administrative work and a lack of professional knowledge.

Chapter 11

In the paper presented in chapter 11, we aimed to assess whether providing information on arthritis self-management through GPs increases the quality of life of patients with osteoarthritis and whether additional case management provided by practice nurses shows better results. In a pragmatic, cluster-randomised controlled, three-armed trial, 1,021 patients from 75 primary care practices in Germany were included. GPs were randomised to intervention group I or II or to a control group. GPs of both intervention groups participated in two peer group meetings. In intervention group II additional case management via telephone was conducted by a practice nurse. The primary outcome was change in quality of life (QoL), assessed by means of the GERMAN-AIMS2-SF. Secondary outcomes were health service utilisation, prescriptions and physical activity. Data were controlled for depression (using PHQ-9) as a potential confounder. 1,021 of 1,125 administered questionnaires were analysed. Compared to the control group, no significant changes occurred in intervention group I with respect to the primary outcome. Performed X-rays dropped significantly ($p=0.050$), while prescriptions of paracetamol increased significantly ($p<0.001$). In intervention group II, significant changes in the AIMS2-SF dimensions "social" ($p<0.001$), "symptom" ($p=0.048$) and "lower body" ($p=0.049$) were identified. X-rays ($p=0.031$) and contacts with orthopaedics ($p=0.044$) decreased while prescriptions of pain relievers increased significantly. To conclude, improving the QoL of arthritis patients using arthritis self-management seems to be challenging. Simply providing information through GPs is not sufficient, but combining it with case management seems to be a promising approach.

Samenvatting

Hoofdstuk 1

Hoofdstuk 1 doet verslag van de resultaten van een kwalitatieve benadering van de oordelen van patiënten, huisartsen en praktijkassistentes over de huidige zorg voor artrosepatiënten in huisartspraktijken in Duitsland. De voornaamste bevindingen waren dat het diagnosticeren van artrose geen uitdaging voor de huisartsen is. Maar bij het beoordelen van de pijn en fysieke handicaps vonden de huisartsen het vaak moeilijk onderscheid te maken tussen klachten voortkomend uit een aandoening van de gewrichten en klachten gerelateerd aan een daarmee samenhangende depressie. Patienten vonden dat ze goed geïnformeerd waren over de degeneratieve aard van de ziekte en mogelijke bijwerkingen van de medicijnen, maar ze misten informatie over individuele consequenties van de ziekte. Daarom waren de belangrijkste zorgen van veel patiënten pijn en angst voor handicaps, wat naar hun mening door huisartsen maar globaal besproken werd. Betreffende pijnbestrijding hadden huisartsen en patiënten een ambivalente houding ten opzichte van non-steroidal anti-inflammatory medicatie (NSAIDs) en opiaten. Pijnbestrijding werd daarom niet uitgevoerd overeenkomstig de heersende richtlijnen. Huisartsen voelden zich gefrustreerd over de invloed van het geven van adviezen over verandering van leefstijl, maar van de andere kant gaven ze toe er geen systematische benadering voor te hebben. Patiënten verklaarden zich bewust te zijn van de invloed van hun leefstijl op artrose maar misten gedetailleerde informatie, bijv. over het doen van oefeningen. Diverse suggesties zijn gedaan voor verbetering.

Hoofdstuk 2

Om de kwaliteit van leven te toetsen zijn valide en betrouwbare instrumenten nodig. Het proces van vertaling en validatie van het meest verspreide instrument om de kwaliteit van leven van artrose patiënten te toetsen, de Arthritis Impact Measurement Scale 2 (AIMS 2) en de korte versie, de AIMS 2-SF worden in hoofdstuk 2 gepresenteerd. Beide instrumenten werden vertaald naar het Duits en aangepast aan de duitse cultuur. Elk van de vragenlijsten werd gestuurd aan 220 patiënten in de eerste lijn met artrose van de knie of heup. 209 (lange versie) vragenlijsten werden teruggestuurd en geanalyseerd. De test-retest betrouwbaarheid werd getest bij 50 (lange versie), respectievelijk 35 (korte versie), willekeurig geselecteerde patiënten. De “fysieke” schaal van de oorspronkelijke AIMS2-SF werd verdeeld in een schaal voor de beperkingen van het bovenlichaam en een voor de beperkingen van het onderlichaam. In beide versies leverden de toetsing van de interne betrouwbaarheid voldoende waarden op;

Cronbach's alpha was 0.77 of hoger voor alle schalen van de lange versie en 0.83 of hoger voor alle schalen, behalve voor “sociale wisselwerking” schaal (0.66 bij de korte versie). De test-retest betrouwbaarheid, uitgedrukt in een intraclass-correlation-coefficient (ICC), kwam boven de 0.90, behalve de “sociale activiteiten” schaal (0.87) in de lange versie. In de korte versie kwam de ICC boven 0.85, behalve bij de “gevoelens/emoties” schaal (0.72). Omdat alleen patiënten met artrose bij de lagere ledematen (arm/been) waren geïncludeerd, traden substantiële bodemeffecten op in de “armfunctie” (28.2%) en de “hand- en vingerfunctie” schaal (29.2) in de lange versie en in de “bovenste ledematen schaal” (33.8%) van de korte versie. De principal factor analyse bevestigde het uitgangspunt van een drie factoren structuur met fysieke, fysiologische en sociale dimensies voor beide versies. Externe validiteit werd beoordeeld door berekening van correlaties met de Western Ontario en Mc Master Osteoarthritis Questionnaire (WOMAC), een visueel analoge schaal voor pijn (pijn-VAS) en radiologische zichtbare ernst van botbeschadiging (getoetst door middel van de Kellgren en Lawrence score). Spearman’s “R” bereikte voldoende waarden voor de daarmee samenhangende WOMAC schalen en de pijn-VAS. Samenhang met de radiologische beoordeling was laag. We concluderen dat onze validiteitsstudies lieten zien dat beide versies van de AIMS2 betrouwbare en valide instrumenten zijn om de kwaliteit van leven te toetsen van patiënten in de 1e lijn die lijden aan artrose. Bij het richten op verschillende vormen van artrose zou de fysieke schaal verdeeld moeten worden in een schaal voor het bovenlichaam en voor het onderlichaam. De gevonden bodem- en plafondeffecten zijn in overeenstemming met kenmerken van de ziekte bij de steekproef van de studie en beperken de betekenis van de vragenlijst niet.

Hoofdstuk 3

Het doel van hoofdstuk 3 was determinanten te toetsen van de inschatting van de huisartsen van de kwaliteit van leven van de patiënten. Derhalve includeerden we 220 patiënten in de eerste lijn met artritis aan de knie of heup die minstens een jaar onder behandeling waren bij hun huisarts. Aan alle huisartsen werd gevraagd om de kwaliteit van leven van de patiënten te toetsen, gebaseerd op de geschiedenis van de patiënt, huidig onderzoek en bestaande röntgenfoto’s d.m.v. een visueel analoge schaal (VAS-schaal), resulterend in waarden tussen 0 en 10. Patiënten werd gevraagd twee vragenlijsten in te vullen: de McMaster Universities Osteoarthritis Index (WOMAC) en de Arthritis Impact Measurement Scale2 Short Form (AIMS2-SF) vragenlijst. De resultaten lieten een significante samenhang

zien tussen zowel de beoordeling door de huisarts, de AIMS2-SF schalen “fysiek” en “symptomen” als de “pijn” schaal van de WOMAC. Een multivariate ordinal regressie analyse toonde aan dat alleen de AIMS2-SF schaal “symptomen” en de röntgenfoto beoordeeld volgens Kellgren en Lawrence een significante invloed hadden op de beoordeling van de kwaliteit van leven door de huisartsen. Concluderend: de resultaten van onze studie laten zien dat de beoordeling van de kwaliteit van leven van patiënten door de huisartsen voornamelijk wordt bepaald door fysieke factoren, namelijk pijn en ernst van de röntgenfoto’s. De resultaten laten ook zien dat sociaal-economische en psychosociale factoren, waarvan bekend is dat ze een substantiële invloed hebben op de kwaliteit van leven, onderschat of gemist worden.

Hoofdstuk 4

Het doel van hoofdstuk 4 was om voorspellers van depressies te vinden in een grote steekproef van patiënten in de eerste lijn met artrose. Patiënten werden opeenvolgend benaderd in 75 huisartspraktijken. Van 1250 uitgedeelde vragenlijsten werden er 1021 teruggestuurd en geanalyseerd. Naast sociodemografische data, medicatie en comorbiditeit werden depressie en artritis getoetst door gebruik van de Patient Health Questionnaire (PHQ-9) en de Arthritis Impact Measurement Scale (AIMS2-SF). Een stapsgewijze multiple lineaire regressie analyse met de PHQ-9-scores als afhankelijke variabelen werd uitgevoerd. Volgens de PHQ-9 bereikten 19.8% van de mannen en 19.2% van de vrouwen een score van 15 of hoger wat in ieder geval wijst op een matige tot ernstige depressie. Het is interessant dat er geen significante verschillen tussen mannen en vrouwen konden worden aangetoond. De sterkste voorspeller voor de mate van depressie was de ervaren pijn en weinig sociale contacten. Andere voorspellers waren lichamelijke beperkingen van zowel het bovenlichaam als het onderlichaam, leeftijd en de BMI. De bevindingen suggereren dat depressie bij artrose patiënten vaker voorkomt en benadrukt de noodzaak voor herkenning en geschikte behandeling. De meeste aangetoonde voorspellers zijn te beïnvloeden en zouden potentiële doelen kunnen zijn in een uitgebreide behandeling van artrose om de vicieuze cirkel van pijn, lichamelijke beperkingen en depressie te doorbreken.

Hoofdstuk 5

In dit hoofdstuk is gekeken naar de invloed van een bijkomende depressie op de kwaliteit van leven en gebruik van de gezondheidszorg door patiënten met artrose.

Data van 1021 patiënten van 75 huisartspraktijken, voortkomend uit het PraxArt project werden geanalyseerd. Metingen bevatten sociodemografische data en een korte versie van de Patient Health Questionnaire (PHQ-9) om een depressie te meten. Data over gebruik van de gezondheidszorg (contacten met huisartsen, orthopedisten en andere aanvullende of alternatieve hulpverleners) werden verkregen door zowel het stellen van vragen als de medische gegevens van de patiënt. De resultaten lieten zien dat patiënten met een depressie significant vaker contact hadden met huisartsen ($p<0.01$) of orthopedisten ($p<0.01$) maar niet met aanvullende of alternatieve hulpverleners. De bevindingen verschaften verschillende inzichten in patronen met betrekking tot het gebruik van de gezondheidszorg. Er kan geconcludeerd worden dat depressieve patiënten de neiging hebben hulpverleners te bezoeken waar ze passief kunnen blijven.

Hoofdstuk 6

Het doel van de studie, gepresenteerd in dit hoofdstuk was de samenhang te toetsen van zwaarlijvigheid met kwaliteit van leven, gebruik van de gezondheidszorg en lichamelijke activiteiten bij een grote steekproef van patiënten in de eerste lijn met artrose. Bij 978 patiënten van het PraxArt project werden lengte en gewicht gemeten en werd de BMI berekend. De AIMS2-SF werd gebruikt om de kwaliteit van leven te toetsen. Data over gebruik van de gezondheidszorg werden verkregen via de medische dossiers van patiënten. Bijkomende depressie werd getoetst middels de Patient Health Questionnaire (PHQ-9). Patiënten werden gegroepeerd in normaal gewicht, overgewicht en zwaarlijvigheid conform de definitie van de WHO en vergeleken middels analyse van de covariantie (ANCOVA). Zwaarlijvige personen en personen met overgewicht bereikten significant hogere scores op de AIMS2-SF onderlichaam schaal, het symptoom, het effect en de werk schaal. Dit impliceert een verhoogde last bij artrose. De PHQ-9 score was significant hoger bij de drie gewichtsgroepen, wat een positief verband aantoonde met BMI en depressie. Bij een verhoogde BMI nam het aantal comorbiditeiten toe en lichamelijke activiteiten namen significant af. Na correctie voor covariaten, bleven contacten met orthopedisten en uitgevoerde röntgenfoto’s significant hoger bij overgewichtpatiënten, maar contacten met huisartsen niet.

Hoofdstuk 7

Pijn vertegenwoordigt een van de belangrijkste voorspellers van kwaliteit van leven bij patiënten met artrose. Maar bij de meeste studies die pijn toetsten

werden belangrijke covariaten zoals depressie, overgewicht of lichamelijke activiteiten niet meegenomen. Daarom wilden we factoren vaststellen die samenhingen met pijnintensiteit in een grote steekproef van artrosepatiënten in de eerste lijn. In een regressiemodel met de “symptoom” dimensie van de AIMS2-SF als afhankelijke variabele bleven 4 factoren over die 47.9% van de variatie verklaarden: Mate van depressie weergegeven in de PHQ-9 score beïnvloedden pijnintensiteit het meest (bèta=0.459, p<0.001). Functionele handicap van de onderste ledematen telde voor een bèta van 0.427 (p=0.003). Een laag opleidingsniveau hing samen met toenemende pijnscores (bèta=-0.321; p=0.029) net als duur van de ziekte (bèta=0.178; p= 0.017). De sociale contacten/netwerk gemeten door de AIMS sociale schaal gaf een bèta aan van 0.211 (p=0.040). Onze studie liet zien dat een variatie van lichamelijke en psychosociale factoren samenhing met pijnintensiteit.

Hoofdstuk 8

Patiënttevredenheid is een belangrijke indicator voor de kwaliteit van zorg gegeven aan artrosepatiënten. Eerdere studies richtten zich op patiënttevredenheid betreffende zekere behandelingen als chirurgische ingrepen of pijnbestrijding. Het doel van de studie in hoofdstuk 8 was de huidige tevredenheid van artrosepatiënten te bepalen en na te gaan of ziektegerelateerde factoren belangrijk zijn voor tevredenheid. Bij de steekproef van 1021 artrosepatiënten werd de kwaliteit van leven gemeten door de AIMS2-SF en werd de patiënttevredenheid gemeten met behulp van het EUROPEP instrument. Een stapsgewijze lineaire regressie analyse met de EUROPEP score als afhankelijke variabele, gecorrigeerd voor het aantal huisartsbezoeken werd uitgevoerd om voorspellers van tevredenheid te toetsen. In tegenstelling tot onze verwachtingen hing alleen de duur van de artrose (bèta=-0.105; p=0.008) en geen andere ziektegerelateerde factor samen met patiënttevredenheid. De voornaamste voorspellers waren de depressiescore (bèta=-0.372; p<0.001), leeftijd (bèta=-0.185; p<0.001), alleen leven (bèta=-0.209; p<0.001), aantal comorbiditeiten (bèta=-0.152; p<0.001).

Hoofdstuk 9

In hoofdstuk 9 werd getoetst in welke mate de huidige zorg voor artrosepatiënten overeenkomt met het Chronic Care Model (CCM) in Duitsland. Bovendien probeerden we mogelijke voorspellers te tonen met een hoge overeenstemming

en op die manier de vraag te bepalen of bepaalde patiënten zorg zouden ontvangen volgens het CCM.
De Patient Assessment of Chronic Illness Care (PACIC-5A) werd gebruikt om te meten volgens het CCM, kwaliteit van leven werd gemeten door middel van de Arthritis Impact Measurement Scale (AIMS2-SF). De PACIC somscore was aanzienlijk lager dan in eerdere studies uitgevoerd in HMO settings in de USA. De stapsgewijze multiple lineaire regressie modellen met de PACIC somscores en de 5A scores als afhankelijken onthulden dat de PACIC scores samenhingen met een hoger opleidingsniveau (bèta=0.421; p=0.008) en lagere leeftijd (bèta=-0.319; p=0.016). De 5A score werd voorspeld door het opleidingsniveau (bèta=0.344; p=0.002), leeftijd (bèta=-0.386; p=0.004) en de PHQ-9 score (bèta=-0.288; p=0.005). Onze resultaten laten zien dat jongere en beter opgeleide patiënten hogere scores bereiken op de PACIC score. Waarom deze patiënten zorg ontvangen die meer overeenkomt met de CCM blijft onduidelijk.

Hoofdstuk 10

In hoofdstuk 10 probeerden we mogelijkheden te laten zien om de praktijkverpleegkundige meer te betrekken bij de zorg voor artrosepatiënten. We hielden kwalitatieve, semi-gestructureerde interviews met 20 huisartsen, 20 praktijkverpleegkundigen en 20 patiënten in de omgeving van Heidelberg. De interviews werden digitaal opgenomen, uitgewerkt en inhoudelijk geanalyseerd met Atlas.ti. Onze resultaten laten zien dat praktijkverpleegkundigen alleen marginaal betrokken zijn bij de behandeling van artrosepatiënten. Zowel huisartsen als patiënten zijn erg sceptisch over het verhogen van de betrokkenheid bij de zorg. Patiënten waren sceptisch over de professionele achtergrond van de verpleegkundigen en vreesden voor een verslechtering van de patiënt-arts relatie. Huisartsen klaagden ook over onvoldoende opleiding van verpleegkundigen betreffende medische kennis. Zij vreesden een tijdgebrek en weinig rendement bij de pogingen tot meer betrokkenheid. Praktijkverpleegkundigen wensten meer betrokkenheid en zagen dit als een waardering van hun rol. De belangrijkste belemmeringen waren een gebrek aan tijd, teveel administratief werk en een gebrek aan professionele kennis.

Hoofdstuk 11

In dit hoofdstuk probeerden we te toetsen of het verschaffen van meer informatie door huisartsen over (‘zelfbehandeling’ van) artritis de kwaliteit van leven van artrosepatiënten verbetert en of aanvullende zorg door de praktijkverpleegkundige

betere resultaten geeft. In een pragmatische, cluster-gerandomizeerde gecontroleerde, drie-armige studie werden 1021 patiënten uit 75 huisartspraktijken in Duitsland geïncludeerd. Huisartsen werden willekeurig toegewezen aan interventiegroep I of II of aan de controlegroep. Huisartsen uit beide interventiegroepen namen deel aan 2 groepsbijeenkomsten. In interventiegroep II werd via de telefoon begeleiding geboden aan patiënten (case management) door de praktijkverpleegkundige. De primaire uitkomsten waren verandering in de kwaliteit van leven, gemeten door de Duitse AIMS2-SF. Secondaire uitkomsten waren gebruik van de gezondheidszorg, voorschriften en lichamelijke activiteiten. Data werden gecorrigeerd voor depressie (middels PHQ-9) als een potentiële confounder. 1021 of 1125 geregistreerde vragenlijsten werden geanalyseerd. Vergeleken met de controlegroep werden er geen significante veranderingen gevonden in interventiegroep I met betrekking tot de primaire uitkomsten. Uitgevoerde röntgenfoto's daalden significant ($p=0.050$), terwijl voorschriften van paracetamol significant toenamen ($p<0.001$). In interventie groep II werden significante veranderingen gevonden in de AIMS2-SF dimensies "sociaal" ($p<0.001$), "symptoom" ($p=0.048$) en "onderlichaam" ($p=0.049$). Röntgenfoto's ($p=0.031$) en contacten met orthopedisten ($p=0.044$) verminderden, terwijl voorschriften en pijnstillers significant toenamen. De conclusie is dat het verbeteren van de kwaliteit van leven van artritispatiënten door 'zelfbehandeling' een uitdaging lijkt. Alleen het verschaffen van informatie via de huisartsen is niet voldoende maar dit combineren met case management lijkt een veelbelovende aanpak.

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Curriculum Vitae

Thomas J. Rosemann was born on 1 July 1969 in Bad Aibling a small town in Bavaria, Germany where he attended primary school and in 1989 finished school receiving his *Hochschulreife* (final exams at the end of secondary education).

From 1989 he studied dentistry at the Ludwig-Maximilians-Universität, Munich moving on to medicine after four semesters.

He graduated in 1996 and during the same year began to work as junior doctor at the Department of General- and Vascular Surgery at the Klinikum Rosenheim, Germany. In July 2000 he switched to internal medicine.

From 2003 he worked at the Department of General Practice and Health Services Research in Heidelberg, Germany, under the direction of Prof Joachim Szecsenyi. He was in charge of scientific projects funded by the German Federal Ministry for Education and Research (*Bundesministerium für Bildung und Forschung*). From 2003 onwards these projects were methodically supported by Michel Wensing and Richard Grol.

In 2006 he gained more experience at the Kaiser Permanente (HMO) health maintenance organisation and at Stanford University (USA).

Also in 2006 he was appointed consultant at the University Clinic of Heidelberg. His *Habilitation* (postdoctoral university degree with lecture qualification) was bestowed on him in 2007, and he received his *venia legendi* for general practice.